From: Morens, David (NIH/NIAID) [E] [b6]
Sent: 4/1/2016 10:29:26 AM
To: William B. Karesh [b6]
CC: Anthony Ramos [b6]
BCC: Morens, David (NIH/NIAID) [E] [b6] ([b6])
Subject: Re: Zika (!)

guys

let me know if there are any glitches

i am down in b6 but back on weekend

d

David M Morens MD
NIAID, NIH
Sent from my iPhone

On Mar 31, 2016, at 16:30, William B. Karesh b6 wrote:

> Thanks !!
>
> On Mar 31, 2016, at 3:32 PM, Anthony Ramos b6 wrote:
>
> David and Billy,
>
> Dr. Fauci's office is going to send me a PDF of the slides for the purpose of sharing. When I receive it I will send to you Billy.
>
> Anthony
>
> **Anthony M. Ramos**
> *Senior Director, Marketing and Development*
>
> EcoHealth Alliance
> 460 West 34th Street – 17th floor
> New York, NY 10001
>
> b6 (direct)
> (mobile)
> 1.212.380.4465 (fax)
> www.ecohealthalliance.org
>
>

On Thu, Mar 31, 2016 at 3:18 PM, William B. Karesh [b6] wrote:

David, Thanks so much again for helping make last night happen. Hope all is well [b6].

Not sure if you know Bob Huffman from EoP S&T - see note below, but he was asking if he could get a copy of the slide deck.

Anthony has it on his computer from last night, but we would not share it without permission.

BK

Begin forwarded message:

From: "Huffman, Robert V CIV USARMY HQDA ASA ALT (US)" [b6]
Subject: Zika (!)
Date: March 31, 2016 at 2:59:44 PM EDT
To: "William B. Karesh" [b6]

Billy, good afternoon. Thanks so much for a superb and riveting program last evening. It was good seeing you, and I also thoroughly enjoyed the preceding (and post-briefing) networking event. All around great night.

Do you know if a copy of Dr. Fauci's slides are available? Frankly, I wasn't overly concerned about Zika prior to his talk, but the information presented did elevate my concerns and interest.

Best Rgds,
bob

Robert V. Huffman, P.E.
Deputy, Biosurveillance Strategy & Policy, Strategic Operations Directorate (SOD)
Joint Program Executive Office for Chemical and Biological Defense (JPEO CBDP)

Executive Secretary, Disease Prediction and Forecasting Working Group
Subcommittee on Biological Defense Research and Development
Committee on Homeland and National Security
National Science and Technology Council
The White House

Office: [b6] | Blackberry: [b6]
[b6]
Medical Countermeasure Systems BioDefense Therapeutics

(MCS-BDTX)
10109 Gridley Road, Bldg 314, 2nd Floor |Fort Belvoir, VA,
22060
www.jpeocbd.osd.mil

From: b6 [b6]
Sent: 3/17/2021 6:31:23 PM
To: b6; Peter Daszak [b6]; Morens, David (NIH/NIAID) [E] [b6]; Keusch, Gerald T [b6]; Aleksei Chmura [b6]
Subject: Peter, Jerry, David Call
Location: b6
Start: 3/17/2021 7:10:00 PM
End: 3/17/2021 8:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Peter Daszak is inviting you to a scheduled Zoom meeting.

Topic: Peter, Jerry, David Call

Time: Mar 17, 2021 03:10 PM Eastern Time (US and Canada)

Join Zoom Meeting

b6

Meeting ID: b6

Passcode: b6

b6 US (New York)

From: Morens, David (NIH/NIAID) [E] [b6 b6]
Sent: 8/24/2021 12:40:04 AM
To: Peter Daszak [b6]
CC: Keusch, Jerry [b6]; Robert Kessler [b6]; Roberts, Rich [b6]
BCC: Morens, David (NIH/NIAID) [E] [b6 b6]
Subject: Re: Francis Collins on CNBC today

u got it exactly right, sorry to say. d

Sent from my iPhone
David M Morens
OD, NIAID, NIH

On Aug 23, 2021, at 20:35, Peter Daszak b6 wrote:

Hello everyone - Not looking forward to the publicity this week with the Intel report coming out sometime soon, but wanted to share a couple of things.

First – here's an interview by Francis Collins on Squawkbox CNBC that makes him come over like a wet lettuce. He goes one way then the other, making sure he sounds somewhat anti-China (they could have been doing mysterious things), but makes it clear NIH didn't fund Gain of Function there.

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The URL is here: https://www.cnbc.com/2021/08/23/covid-origin-nih-director-doesnt-rule-out-that-virus-could-have-leaked-from-lab.html

NIH director says Covid likely came from nature, but doesn't rule out it could have escaped from lab

PUBLISHED MON, AUG 23 202112:53 PM EDTUPDATED MON, AUG 23 20211:08 PM EDT

Rich Mendez@RICHMENDEZCNBC

KEY POINTS

President Joe Biden gave the U.S. intelligence community 90 days to investigate Covid's origins and report the findings, which are due Tuesday.

Through a grant to non-profit EcoHealth Alliance, the NIH funded research at the Wuhan Institute of Virology to study how bat viruses could infect humans.

Collins said the research didn't meet the technical definition of so-called gain-of-function research.

The director of the National Institutes of Health said Monday it appears Covid-19 originated from an animal, but he didn't rule out the possibility that scientists at the Wuhan Institute of Virology were secretly studying it and that it could have leaked out from there.

It's still unknown if the virus leaked out of a Wuhan lab, NIH director Dr. Francis Collins said Monday in an interview on CNBC's "Squawk Box," adding that the World Health Organization's investigation into the origin of the coronavirus has gone "backwards."

"The vast evidence from other perspectives says no, this was a naturally occurring virus," Collins said. "Not to say that it could not have been under study secretly at the Wuhan Institute of Virology and got out of there, we don't know about that. But the virus itself does not have the earmarks of having been created intentionally by human work."

The WHO investigation has been made harder by China's refusal to participate, says Collins.

"I think China basically refused to consider another WHO investigation and just said 'nope not interested'," Collins told CNBC's Squawk Box.

"Wouldn't it be good if they'd actually open up their lab books and let us know what they were actually doing there and find out more about those cases of people who got sick in November of 2019 about which we really don't know enough," Collins said.

U.S. intelligence reports first reported by the Wall Street Journal indicated that in November 2019, three workers at the Wuhan Institute of Virology fell ill with symptoms similar to those seen in Covid-19 infections, a report that China said was "completely untrue."

About three months ago, President Joe Biden initiated an investigation of his own and gave his intelligence community 90 days to further the investigation the virus' origins and report the findings. The deadline is Tuesday.

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Most of the information gathered will likely remain classified, but some information from the report will be released, according to Collins.

"We don't know what they're going to come up with either, but we're intensely interested," Collins said.

Collins also weighed in on the debate over whether or not the U.S. funded so-called gain-of-function research at the Wuhan lab, a debate that Republican Sen. Rand Paul of Kentucky and medical advisor to the president, Dr. Anthony Fauci, have engaged in time and time again. Gain-of-function research is when scientists take a pathogen and make it more contagious, deadly or both to study how to combat it.

"The kind of gain-of-function research that's under very careful scrutiny is when you take a pathogen for humans, and you do something with it that would enhance its virulence or its transmissibility," Collins said. "They were not studying a pathogen that was a pathogen for humans, these are bat viruses."

Some of the research at the Wuhan Institute of Virology that was funded, in part, by the NIH through a grant to non-profit EcoHealth Alliance studied how bat viruses could infect humans.

"So by the strict definition, and this was look at exquisitely carefully by all the reviewers of that research in anticipation that this might come up, was that this did not meet the official description of what's called gain-of-function research that requires oversight," Collins said. "I know this has gotten lots of attention, but I think it's way out of place."

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: b6
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Morens, David (NIH/NIAID) [E] b6
Sent: Monday, August 23, 2021 5:33 PM
To: Peter Daszak (b6) b6; Keusch, Jerry (b6) b6; Kessler, Robert (b6) b6
Subject: FW: Vice: Why China Is Struggling to Make the Lab Leak Theory Go Away

David

David M. Morens, M.D.
CAPT, United States Public Health Service
Senior Advisor to the Director
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520

☎ b6 (assistant: Whitney Robinson)
301 496 4409
b6

From: Folkers, Greg (NIH/NIAID) [E] b6
Sent: Sunday, August 22, 2021 12:29 AM
Subject: Vice: Why China Is Struggling to Make the Lab Leak Theory Go Away

Why China Is Struggling to Make the Lab Leak Theory Go Away

U.S. spy agencies are about to report on COVID-19's origins, but don't hold your breath.

by Alan Wong
by Viola Zhou
August 20, 2021, 9:38am

Robert Redfield has a lot of questions. The virologist and former director of the U.S. Centers for Disease Control and Prevention wants to know what happened at the Wuhan Institute of Virology, especially in the months before the emergence of COVID-19 in the same city. But China's answers didn't satisfy him.

"On Sept. 12, 2019, coronavirus bat sequences were deleted from the institute's database. Why? It changed the security protocols for the lab. Why? It put out requests for more than $600 million for a new ventilation system. What prompted this new need?"

Redfield, who believes that the coronavirus escaped from the lab in Wuhan, asked those questions in the *Wall Street Journal* on Sunday, alluding to the possibility that something bad happened at the facility as early as September that year and caused a pandemic that has killed more than 4 million people worldwide. To bolster this view, he said a Harvard study of satellite images revealed a shutdown of traffic around the Wuhan lab around that time and that hospital parking lots in the city were filling up—signs, perhaps, of a lab accident and a subsequent surge in sick people.

But almost all of those insinuations are disputed, inaccurate, or just plain wrong.

The opinion article offers a stark illustration of the limits of circumstantial evidence as the search for the origins of COVID-19 enters a contentious new phase.

U.S. spy agencies are preparing to release a report on their findings on whether the pandemic started from human contact with an infected animal or a laboratory accident in China. The report is expected no

later than next week, after President Joe Biden in May gave the U.S. intelligence community a 90-day deadline to further collect and analyze information that could "bring us closer to a definitive conclusion" on the origins of COVID-19.

But China is not keen to cooperate. Further muddling the search is Beijing's renewed push of an unsubstantiated, alternative theory that the virus could have originated in a U.S. army lab at Fort Detrick, Maryland. The move has only fueled suspicions that the Chinese government is hiding something.

Unless U.S. spies uncovered substantial evidence—such as proof that the Wuhan lab possessed the virus that caused COVID-19 or evidence that it created the virus—the debate on the pathogen's origins is likely to persist.

Redfield co-authored the *Journal* article with Marc Siegel, a physician and *Fox News* contributor who last March said the coronavirus was no worse than the flu. It was riddled with mistakes.

For example, the planned ventilation system upgrade at the Wuhan Institute of Virology cost about $600,000, not $600 million as the authors stated. The figure was corrected on Friday, a day after VICE World News emailed questions to the *Journal*'s opinion desk. That number came from a report by Republicans that exaggerated the amounts of several other projects by orders of magnitude and has been cited in several other prominent news outlets.

The Trump-appointed former director of the CDC apparently also misattributed the findings of a military contractor's report to Harvard. The Harvard study he links to analyzed satellite images of hospital parking lots in Wuhan, but it did not once mention the Wuhan Institute of Virology. It was also criticized for its poor dataset, abuse of statistical methods, and mistranslation.

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These are just a few examples, from one article, showing the challenges of investigating the origins of the coronavirus without being in China and without the country's full cooperation.

The closest thing to a field study the world has seen was the World Health Organization (WHO) trip to China early this year, but the global health body has complained about not being able to access the complete raw data from the early COVID-19 patients that could give researchers insights into how the virus emerged.

Last month, the WHO chief urged Beijing to share the data, but Chinese officials said the information could not be disclosed due to patients' privacy. Some scientists are not convinced by the argument, citing the possibility of disclosing the data while keeping the patients' anonymous.

Beijing's obsession with a theory that the coronavirus could have been brought into China through frozen food imports has also raised doubts. Officials have kept calling for more research into such potential cold-chain transmission, although few scientists abroad have found it credible enough to justify further investigation.

"In my opinion, it's even less likely than lab origin," Angela Rasmussen, a virologist at the University of Saskatchewan in Canada, told VICE World News. Rasmussen, who has argued in favor of a natural origin of the coronavirus, said the Chinese government might be trying to distract people from the wildlife trade that could have led to a virus zoonotic spillover.

Scientists say only greater transparency will help Chinese authorities fend off all these suspicions. "We are being asked to take their words for it, without seeing any data," said Alina Chan, a biologist at the Broad Institute in Cambridge, Massachusetts, who has promoted the lab leak hypothesis. Chan told VICE World News she would like to see all of the sequences of the pathogens that were processed at the Wuhan lab. If the data could not be made public, she said, they should at least be reviewed by an international team of scientists.

"This situation is setting precedents for how future outbreaks are tracked," she said. "If every single country does this, and refuses to let international investigators check where the virus came from, we would just be facing a future where viruses are just exploding everywhere, and we are just getting a new pandemic every five or ten years."

Some other scientists still maintain that the lab leak theory is unlikely, in contrast with what they have called a "substantial body of scientific evidence" supporting a natural origin for the coronavirus, according to a peer-reviewed paper published in *Cell* this week.

Still, with few new data points to inform the origins probe, scientists on both sides of the debate have called for greater transparency.

WHO Director-General Tedros Adhanom Ghebreyesus in July said the lack of raw data on the early days of the outbreak was hampering the investigations into the origin of the virus and urged China to be more transparent. Tedros suggested further studies into Chinese laboratories in the next phase of studies.

But the Chinese government would not feel comfortable with this degree of transparency. The Communist Party leadership is used to conducting investigations and making decisions behind closed doors, and sees the call for openness as a political threat.

"That is not atypical in China's crisis management," Yanzhong Huang, a senior fellow for global health at the Council on Foreign Relations, told VICE World News. "The U.S. could push for more transparency, but they fail to recognize that the lack of transparency itself is part of the authoritarian governance in the country."

This mindset could hurt China's reputation—the pandemic is not a small crisis but one that has upended almost everyone's life. "Even if the virus is caused by a natural spillover event," Huang said, "when you don't show transparency, when you are perceived as unwilling to share the data, people naturally will think you have something to hide."

The Chinese government has remained intransigent to the mounting calls for more transparency.

At the press conference last month, Chinese officials said they were "shocked" to hear about WHO's proposal for fresh audits into Chinese labs, adding the suggestion indicated "disrespect for common sense and an arrogant attitude toward science."

The same month, state media quoted a Facebook post by a self-claimed Swiss biologist named Wilson Edwards as saying that researchers faced intimidation from the U.S. for supporting the WHO-China origin-tracing study. The Swiss embassy said no such person exists.

It's unclear whether the U.S. intelligence probe, which was condemned by Chinese state media as a "political witch-hunt," would yield anything more than circumstantial evidence.

By the time a preliminary report was drafted, the intelligence community was still divided over the lab leak theory and the natural origin one, CNN reported this month. The outlet cited a source as saying that the draft contained "nothing too earth shattering."

In September 2019, the Wuhan Institute of Virology shut off public access to its database, which holds thousands of genetic sequences of bat coronaviruses it studied.

Shi Zhengli, director of the Center for Emerging Infectious Diseases at the institute, said the online database was shut down after cyberattacks—believe it or not, that's the answer to ex-CDC director Robert Redfield's first question. But almost two years later, the database remains offline. It's no wonder that people are asking questions.

Follow Alan Wong and Viola Zhou on Twitter.

From: Peter Daszak [b6]
Sent: 8/24/2021 3:51:46 AM
To: Roberts, Rich [b6]; Morens, David (NIH/NIAID) [E] [b6 b6]; Keusch, Jerry [b6]; Robert Kessler [b6]
Subject: RE: Francis Collins on CNBC today

Yes, you're right – he didn't throw us under the bus completely to be fair…

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: b6
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Roberts, Rich b6
Sent: Monday, August 23, 2021 9:06 PM
To: Peter Daszak b6; Morens, David (NIH/NIAID) [E] b6; Keusch, Jerry b6; Robert Kessler b6
Subject: RE: Francis Collins on CNBC today

Peter:

It could have been much worse.

Rich

Richard J. Roberts
New England Biolabs
240 County Road
Ipswich, MA 01938-2723

USA
Tel: b6
Fax: (978) 412 9910
email: b6

From: Peter Daszak b6
Sent: Monday, August 23, 2021 8:35 PM
To: Morens, David (NIH/NIAID) [E] b6; Keusch, Jerry b6; Robert Kessler b6; Roberts, Rich b6
Subject: Francis Collins on CNBC today

EXTERNAL SENDER

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NIH director says Covid likely came from nature, but doesn't rule out it could have escaped from lab

PUBLISHED MON, AUG 23 202112:53 PM EDTUPDATED MON, AUG 23 20211:08 PM EDT
Rich Mendez@RICHMENDEZCNBC

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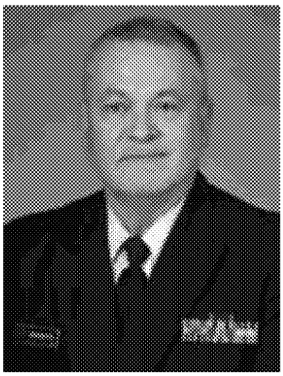
Subject: FW: Vice: Why China Is Struggling to Make the Lab Leak Theory Go Away

David

David M. Morens, M.D.
CAPT, United States Public Health Service
Senior Advisor to the Director
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520

☎ b6 (assistant: Whitney Robinson)
301 496 4409
b6



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"This situation is setting precedents for how future outbreaks are tracked," she said. "If every single country does this, and refuses to let international investigators check where the virus came from, we would just be facing a future where viruses are just exploding everywhere, and we are just getting a new pandemic every five or ten years."

Some other scientists still maintain that the lab leak theory is unlikely, in contrast with what they have called a "substantial body of scientific evidence" supporting a natural origin for the coronavirus, according to a peer-reviewed paper published in *Cell* this week.

Still, with few new data points to inform the origins probe, scientists on both sides of the debate have called for greater transparency.

WHO Director-General Tedros Adhanom Ghebreyesus in July said the lack of raw data on the early days of the outbreak was hampering the investigations into the origin of the virus and urged China to be more transparent. Tedros suggested further studies into Chinese laboratories in the next phase of studies.

But the Chinese government would not feel comfortable with this degree of transparency. The Communist Party leadership is used to conducting investigations and making decisions behind closed doors, and sees the call for openness as a political threat.

"That is not atypical in China's crisis management," Yanzhong Huang, a senior fellow for global health at the Council on Foreign Relations, told VICE World News. "The U.S. could push for more transparency, but they fail to recognize that the lack of transparency itself is part of the authoritarian governance in the country."

This mindset could hurt China's reputation—the pandemic is not a small crisis but one that has upended almost everyone's life. "Even if the virus is caused by a natural spillover event," Huang said, "when you don't show transparency, when you are perceived as unwilling to share the data, people naturally will think you have something to hide."

The Chinese government has remained intransigent to the mounting calls for more transparency.

At the press conference last month, Chinese officials said they were "shocked" to hear about WHO's proposal for fresh audits into Chinese labs, adding the suggestion indicated "disrespect for common sense and an arrogant attitude toward science."

The same month, state media quoted a Facebook post by a self-claimed Swiss biologist named Wilson Edwards as saying that researchers faced intimidation from the U.S. for supporting the WHO-China origin-tracing study. The Swiss embassy said no such person exists.

It's unclear whether the U.S. intelligence probe, which was condemned by Chinese state media as a "political witch-hunt," would yield anything more than circumstantial evidence.

By the time a preliminary report was drafted, the intelligence community was still divided over the lab leak theory and the natural origin one, CNN reported this month. The outlet cited a source as saying that the draft contained "nothing too earth shattering."

In September 2019, the Wuhan Institute of Virology shut off public access to its database, which holds thousands of genetic sequences of bat coronaviruses it studied.

Shi Zhengli, director of the Center for Emerging Infectious Diseases at the institute, said the online database was shut down after cyberattacks—believe it or not, that's the answer to ex-CDC director Robert Redfield's first question. But almost two years later, the database remains offline. It's no wonder that people are asking questions.

Follow Alan Wong and Viola Zhou on Twitter.

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From: Peter Daszak [b6]
Sent: 7/27/2021 6:23:29 PM
To: Morens, David (NIH/NIAID) [E] [b6]; Keusch, Jerry [b6]
Subject: RE: Fox: Biden to visit intelligence community as investigation into COVID-19 origin continues

Another one I hadn't seen – key comment from CIA Director:

Burns, though, admitted it is "possible" that the intelligence community "may never be able to come to a definitive judgment" on the origins of COVID-19, but stressed that it is "not going to be for lack of hard work or effort on this issue to try to uncover as much as we can about what happened."

In other words – Biden successfully kicked the can down the road to the end of summer. Hopefully it'll reduce some of the ardor of the right wing nutjobs who keep pushing this. The fact that publications have now come out showing multiple new viruses in bats related to SARS-CoV-2, evidence of live wild CoV reservoir mammals in the markets, a review by eminent virologists, etc. etc. should help, but people aren't actually interested in the truth at this point I expect.

Cheers,

Peter

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Morens, David (NIH/NIAID) [E] b6
Sent: Tuesday, July 27, 2021 12:05 PM
To: Peter Daszak (b6) b6; Keusch, Jerry (b6) b6
Subject: FW: Fox: Biden to visit intelligence community as investigation into COVID-19 origin continues

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From: Folkers, Greg (NIH/NIAID) [E] b6
Sent: Tuesday, July 27, 2021 11:43 AM
Subject: Fox: Biden to visit intelligence community as investigation into COVID-19 origin continues

White House
Published 1 hour ago

Biden to visit intelligence community as investigation into COVID-19 origin continues

Intel community has less than 30 days before Biden's deadline on COVID-19 investigation

By Brooke Singman | Fox News

China refuses to allow independent probe as COVID origins pressure mount

Fox News correspondent Rich Edson has the latest on China's accountability on 'Special Report'

President Biden is set to visit the Office of the Director of National Intelligence Tuesday afternoon amid the intelligence community's ongoing investigation into the origins of COVID-19.

The intelligence community is "aggressively" investigating the origins of COVID-19, after the president in May revealed that the U.S. intelligence community had "coalesced around two likely scenarios" for the origins of COVID-19, "including whether it emerged from human contact with an infected animal or from a laboratory accident," and asked for "additional follow-up."

INTEL COMMUNITY 'AGGRESSIVELY' INVESTIGATING ORIGINS OF COVID-19

The president asked the intelligence community to "redouble their efforts to collect and analyze information that could bring us closer to a definitive conclusion, and to report back to me in 90 days," Biden said.

It has been 62 days since Biden's announcement.

Last week during an interview with NPR, CIA Director Bill Burns said the intel community at this point "cannot offer a definitive conclusion about whether this originated in a lab accident or whether it originated in a natural transmission from infected animals to human beings."

"We are working very hard on this," Burns said. "It's not an academic problem. I mean, this affects not only the hundreds of thousands and millions of people around the world who have been affected by this, but it's also absolutely

essential as we think ahead, not just to the United States, but in other parts of the world – about how do you prevent another pandemic crisis of this magnitude."

Burns said it is "extremely important to get to the bottom of this."

CHINA REFUSAL TO SUPPORT WHO COVID ORIGINS PROBE ACCELERATED BIDEN ANNOUNCEMENT ON US INVESTIGATION: OFFICIAL

"And the two realities are that the Chinese government has not been transparent, has not fully cooperated in the WHO's investigation initially — and it's more recently suggested it's going to refuse to cooperate in a follow up as well," Burns said. "And that is deeply unfortunate."

Video

He added: "We will continue to do everything we can to collect on this, work with the rest of the intelligence community and provide the best answers we can on this."

Burns, though, admitted it is "possible" that the intelligence community "may never be able to come to a definitive judgment" on the origins of COVID-19, but stressed that it is "not going to be for lack of hard work or effort on this issue to try to uncover as much as we can about what happened."

BIDEN: INTEL COMMUNITY TORN BETWEEN 'TWO LIKELY SCENARIOS' ON COVID-19 OUTBREAK SOURCE

Meanwhile, the president is set to address the intelligence community workforce and its leadership during his visit to thank them for their work in what the White House described as a "challenging time" for the community during the Trump administration.

"He's someone who believes in the role of the intelligence community of civil servants," White House press secretary Jen Psaki said Monday in previewing the president's visit. "He believes they are the backbone of our government, and certainly he'll make that clear."

Psaki was asked whether Biden would have a different or contrasting message compared to his predecessor, former President Trump, who was skeptical of the intelligence community throughout his administration due to the investigation into whether his campaign colluded with the Russians to influence the 2016 presidential election, and the subsequent investigation into the origins of that probe and whether it began improperly.

Psaki on Monday replied, saying reporters can "make the inherent contrast" but said she did not believe that would be a "central part of his message" during Biden's visit to ODNI.

Brooke Singman is a Politics Reporter for Fox News. Follow her on Twitter at @BrookeSingman.
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From: Peter Daszak [b6]
Sent: 7/8/2021 5:18:28 PM
To: Morens, David (NIH/NIAID) [E] [b6]; Keusch, Jerry [b6]
Subject: RE: NAS workshop: Potential Benefits of Gain-of-Function Research https://bit.ly/3jY9zjM

Great to see this – I haven't had chance to read up on the pro-GoF arguments, and this is a good start…

Cheers,

Peter

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Morens, David (NIH/NIAID) [E] b6
Sent: Thursday, July 8, 2021 11:04 AM
To: Peter Daszak (b6) b6; Keusch, Jerry (b6) b6
Subject: FW: NAS workshop: Potential Benefits of Gain-of-Function Research https://bit.ly/3jY9zjM

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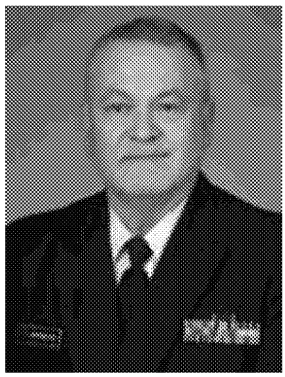

From: Folkers, Greg (NIH/NIAID) [E] b6
Sent: Thursday, July 8, 2021 10:12 AM
To: NIAID OD AM <NIAIDODAM@niaid.nih.gov>
Subject: NAS workshop: Potential Benefits of Gain-of-Function Research https://bit.ly/3jY9zjM

Potential Benefits of Gain-of-Function Research

The benefits that have resulted from the billions of dollars invested in biomedical research over the past several decades are seldom disputed. Biomedical research has made enormous contributions to the understanding of disease and the development of cures through the creation of countless innovations for improving and protecting human health, including new animal models and more effective vaccines and drugs. However, as pointed out by Dr. Ronald Atlas, from the University of Louisville and one of the symposium planning committee members, the benefits of basic biomedical research for medical practice and public health may be long term and their value not immediately evident. The results of particular types of research cannot always be predicted, and benefits are often serendipitous. Because it is not possible to predict what breakthroughs may occur as a result of fundamental research, it is impossible to quantify the benefits of fundamental research for risk/benefit analyses. Long-term research benefits are achievable, but it is not possible to specify what these are when the research is initiated.

Research using Gain-of-Function (GoF) techniques is no different with respect to what it can achieve in the long term, at least according to many of the symposium participants. Atlas noted that, although there was no attempt to achieve a consensus, no disagreement was voiced to the repeated claims of various presenters that in the short term GoF research is helpful for adapting viruses to growth in culture and for developing essential animal models for emerging pathogens, such as Middle East Respiratory Syndrome coronavirus (MERS-CoV), and escape mutations to understand drug resistance and viral evasion of the immune system. In the long-term it may also allow the generation of information that is not obtainable through other methods, but whether all the long-term benefits envisioned for GoF research will actually be realized is still unclear. Vaccine producers in particular disagree on whether GoF methods are essential for vaccine development, so the contributions of GoF research to vaccine development need careful evaluation. Increasing reliance on gene sequences to predict phenotypes may increase GoF research's importance over time. As was clear from the presentations in Session 4 of the symposium, there is wide recognition that it is not yet possible to predict phenotype from genotype, but Dr. Philip Dormitzer, from Novartis Vaccines and a member of the symposium planning committee, noted that as more genotype-phenotype linkages are established, it may enable keeping certain viral characteristics out of vaccine strains.

Two symposium sessions were devoted to presentations on the potential benefits of GoF research, one focusing on the role of GoF in surveillance, detection, and prediction and the other on its role in treatment and response.

Go to:

SURVEILLANCE, DETECTION, AND PREDICTION

The first presentation in Session 4 was given by Dr. Stacey Schultz-Cherry, St. Jude Children's Research Hospital, who discussed the information garnered from GoF studies about what she believes are its public health implications. Her home institution is one of five National Institute of Allergy and Infectious Diseases (NIAID) Centers of Excellence for Influenza Research and Surveillance in the United States and focuses on the animal-human interface. St. Jude is also a World Health Organization (WHO) collaborating center for studies on the ecology of influenza and is part of a global influenza surveillance and response system that includes six WHO collaborating centers and 144 national influenza centers throughout the world. St. Jude collaborates with colleagues in the animal health sector and their main role is to decide on the influenza strains that are incorporated into the seasonal flu vaccines. They also decide whether vaccines or candidate vaccine viruses are needed for emerging zoonotic threats.

The national influenza centers conduct viral strain surveillance throughout the year, looking at the genetic information from human as well as emerging zoonotic viruses. Every February and September, representatives from the WHO centers and central regulatory laboratories as well as animal health experts go through the surveillance data to decide on which viruses to choose as vaccine strains. This information is given to the vaccine manufacturers and regulatory agencies, and 6-9 months later the vaccines become available. She described many of the complexities of the process. She noted, in particular, that determining the function of amino acid changes in the viruses circulating in the field is one of the key tasks. As an example, she discussed an ongoing outbreak of H5 viruses in Cambodia. Through GoF research, it has been determined that the presence of certain genetic markers in the outbreak strain suggested that this particular virus could be more readily transmitted, at least in ferrets. This information has provided the persuasive factor to move forward with the development of a vaccine.

Schultz-Cherry noted that GoF research-derived information is also used for risk assessment. The U.S. Centers for Disease Control and Prevention has developed a risk assessment tool, the Influenza Risk Assessment Tool, to rank the risk associated with particular viruses. She stated that the result of using the Tool is not a prediction of the next pandemic, but rather an objective means of prioritizing viruses for future risk management. The Tool looks at the properties of a virus. What kind of receptors does it bind to? Is it more mammalian or avian? Does it transmit in animal models, or does it have molecular signatures that would suggest transmissibility? What is its genomic variation? She stated that all of this information, especially the molecular determinants of transmissibility, has been generated through GoF studies at some point, perhaps even as far back as the 1970s. She stated that the ability to prioritize is important because of limited resources; vaccines cannot be made for every new emerging virus.

Schultz-Cherry's final points dealt with the limitations of these studies. Phenotype still cannot be predicted from genotype. We may know a lot from studies of particular amino acid changes in one strain of virus that may not apply to another strain. She noted that opponents of GoF research have said that this is a reason to not continue this work. She would argue, however, that inability to predict phenotype is precisely why GoF studies must continue so that eventually this inability can be overcome.

During the discussion following the presentations, Schultz-Cherry was asked what is the trajectory of the information being used for vaccine candidate selection? She explained that the risk assessment tool is continually updated to add new information about molecular determinants of virulence and transmissibility. She believes that the more information we have, the better we will be able to predict the risk of a pandemic and then use that prediction to prioritize vaccine strain selections and make the vaccines available.

Dr. Christophe Fraser of Imperial College, London next spoke about potential pandemics. He began by stating that he would scrutinize the benefits of GoF experiments using a narrow definition of GoF as dealing with the transmissibility of the highest risk potential pandemic pathogens (PPPs). He is the Deputy Director of the Center for Outbreak Analysis and Modeling, which is also a WHO Collaborating Centre for Infectious Disease Modelling, located in London. He and his colleagues at the Centre have worked on the Severe Acute Respiratory Syndrome (SARS) outbreak, the initial response to the 2009 influenza pandemic, and have synthesized a variety of surveillance, neurological, and epidemiological information. In 2014, their work turned to both MERS, for which they were trying to quantify its transmissibility to humans, and Ebola as part of the WHO response team. He noted that, on a global scale, the interventions in the event of an outbreak are quite simple—well-organized classical public health tools. The key aspect is timeliness, and the classical tools are diagnostics, social distancing, and risk communication. Probably the area most lacking at the moment on a global scale is rapid diagnostics to allowed triaging of people, which has been made very clear with Ebola. Data systems, multidisciplinary validation, and sharing of data and samples are all required. There is also a huge role for basic science, but once an epidemic has started, the value of information from this limited realm of GoF work on transmissibility is unclear. The role of such work is clearly going to be in predicting pandemics. He stated, however, that H5N1, H7N9, MERS, and Ebola had all clearly been identified as threats prior to any GoF-PPP experiments, although this is less the case for the 2009 H1N1 outbreak and SARS. Nevertheless, the failure to predict outbreaks of the first four pathogens he listed was due to surveillance gaps, not a lack of understanding. Of the viruses that emerged in 2009, there were no closely related viruses found by surveillance in any swine populations for 12 years prior to the emergence of H1N1. MERS also emerged from a complete surveillance gap.

The next utility that has been claimed for GoF research-derived data is for predicting emergence. The data from the two experiments on H5N1 transmissibility were plugged into a model by Colin Russell and Derek Smith (Russell et al., 2012), who concluded that it is not possible to calculate the level of pandemic risk precisely because of uncertainties in some aspects of the biology. Fraser stated that he very much endorses that statement; it is not possible to calculate the level of risk from the mutational landscape. The aim in Russell et al. (2012) was to conduct basic science to understand the factors that increase or decrease risk, not to assess the actual risk. Russell's work built on earlier work that attempted to predict pandemics. The earlier work from Jamie Lloyd Smith tried to establish a general rule, which is that infection begets transmission and transmission begets epidemics. Things that can cause transmission are much more likely to result in epidemics than things that are not already transmissible.

The WHO uses an empirical, rather than a theoretical, approach, meaning that alarm bells should be based on human cases and clusters and the key is surveillance and sharing of data. However, as Fraser had previously noted, there are limitations, especially given that for many years there was reluctance to acknowledge clusters of infections because of the fear of escalating the WHO alert levels and the resulting consequences. In terms of surveillance and response, it is of course very useful to know what viruses are out there, but it is promptness that is critical. To contain an epidemic at its source, there is a window of days in which to intervene. Once the epidemic gets going, the scale of the problem will double every week. The most suitable response would be based on the timely reporting of cases.

Fraser believes that pre-pandemic vaccine strain selection is the crux of the argument. Timely development of vaccines could be transformative. Vaccine seed stocks can speed this up, but there are other rate-limiting steps, especially

international agreements on the regulation and conduct of human trials. He also believes that the objectives should be to:

- prioritize strains with evidence of infection and transmission;
- cover antigen space, and monitor antigenic drift;
- plug gaps in surveillance;
- make more/faster seed stocks (Dormitzer et al., 2013)?

Fraser concluded with the following:

- The direct benefits for enhanced surveillance and model-based prediction of GoF experiments with PPP should not be overstated.
- The indirect benefits of basic science are likely huge, but the rationale for working with dangerous pathogens requires benefits that outweigh risks and opportunity costs.
- The benefits of GoF with PPP for pre-pandemic vaccine production should be probed in depth.
- The risks are real and present (Lipsitch and Inglesby, 2014).

A participant asked Fraser about what he would require to be confident about using data from GoF or other experiments in his modeling? He responded that the tools required for this lengthy, although worthwhile, journey must be available. The issue centers on the risk taken at the beginning of the journey. Earlier in the morning, Fineberg mentioned that, by their nature, pandemics provide many years to think about the tools but only infrequent and limited time to acutally test them. Weather forecasting has improved dramatically because weather forecasters can test their models daily and receive many complaints when they are wrong. The situation with pandemics is not like that.

Dr. Colin Russell of Cambridge University Infectious Diseases responded to the two previous presentations as the last speaker of Session 4. He noted that both of the previous speakers touched on the ability to predict risks for pandemic viruses and on the ability to produce vaccines in a timely manner, and to ensure that there are enough vaccines to go around and provide a chance to mitigate the early spread of disease. However, the more we learn about nature, the more we understand that there are a vast number of undescribed viruses out there, many known only through sequence data. He stated that genotype to phenotype prediction is one of the holy grails of influenza biology research. However, much more research is required to reach this goal. He referred to a National Institutes of Health workshop for which he was lead organizer in the fall of 2013 that brought together experts in virology, epidemiology, and other fields. It included participants from both sides of the GoF debate, and a key focus of the meeting was to rectify the limitations in the ability to make inferences about the phenotype of influenza viruses from genetic sequence data alone. A full report of this workshop was published in October (Russell et al., 2014). A key question in the discussions was whether the effects of mutations are dependent on the viruses in which they occur. A variety of studies suggest that the effects of particular mutations are strongly likely to depend on the genetic context in which they appear. First, in 2006 Jane Stevens, Ian Wilson, and others published a paper in the journal *Science* (Stevens et al., 2006) about GoF research, investigating the potential for a virus to switch receptor binding from avian-like to human-like. This work was among the first to demonstrate that single amino acid substitutions could cause such a switch. But the authors concluded that knowledge of genetic changes in circulating virus isolates by themselves obviously cannot be used to predict the impact of receptor binding specificity, let alone affect the results of future mutations (Stevens et al., 2006). It is worth bearing in mind, Russell stated, that there is a great degree of genetic diversity in the H5 virus. Other studies have found that the effects of mutations in other H5 viruses depend on the clade of H5 viruses in which the substitutions were produced. These residues alone cannot be used as reference points with respect to specificity in H5N1 strains, but when combined with other data, the presence or absence of these mutations can be informative. None of this should be in any way construed to undermine the value of the studies, but highlight the impressive need for further work. In short, Russell believes that, given the incomplete state of knowledge, there is a risk of overestimating what is known based on sequence data alone. Focusing too much attention on the presence or absence of particular mutations may cause other mutations or even other traits yet to be identified to be overlooked.

Gavin Huntley-Fenner asked the panel members what sort of public health system would be needed to justify the status quo and whether the risks and benefits of GoF research are balanced from this public health perspective. Fraser

answered that transmissible viruses makes GoF research a very special case. In terms of general basic science, we never have to justify that to the same degree, luckily, because otherwise we would find it difficult to move forward. Basic science is a much broader portfolio where the risks are very small. The real crux of the GoF issue is separating out that very small number of experiments. We need a much wider frame for all experiments, where occupational health risks are not an order of magnitude higher than public health risks.

Laurie Garrett of the Council on Foreign Relations commented to Schultz-Cherry that her statement that the risk assessment model would be adjusted differently if H5 was in Canada speaks to the core of the whole problem. Risk is about rich people, which is about 5 percent of the global population, if that. She stated that we have never once delivered vaccine to poor people around the world for any epidemic/pandemic situation in the history of the planet, have never delivered clinical tools, and have never delivered diagnostic tools. Garrett had just come out of quarantine for Ebola, and there is nothing that can possibly be called a rapid diagnostic available for Ebola. So when the Council on Foreign Relations reviewed the whole question of GoF use and issued its memorandum to the White House (available at www.CFR.org), it concluded that the most fundamental problem is that the International Health Regulations have never been fully implemented. Garrett stated that none of the wealthy nations has assisted poor nations to raise them to capacity and that "none of the benefits will ever be available to the majority of planet Earth and none of them are getting the toolkit to minimize or mitigate risk. We are having a very American conversation that excludes the rest of the planet."

Schultz-Cherry responded that her remark about having H5 in Canada was designed to make people think about risk versus benefit and to reflect that doing more work can democratize the surveillance process. With more work, it could become cheap and easy to assess the threat of viruses. If this could be done, we could radically change the way we do surveillance worldwide and we would not have the same sort of geographic distributional issues that are of concern now.

Dr. Gregory Koblentz, George Mason University, asked Schultz-Cherry about the proven accuracy of the risk assessment tool used for selecting flu strains for yearly vaccines. She, in turn, called on Dr. Ruben Donis of the CDC to comment more about the risk assessment tool. Donis noted that the risk assessment tool is a product of the global community of scientists working on both human and animal health. It is a product of the realization of the gaps in surveillance that were noted in Fraser's presentation. It was developed to ensure that we have a comprehensive way of evaluating all the possible viruses that are circulating in animals that could reassort, recombine, and change the phenotype and eventually emerge as pandemic viruses. The tool attempts to develop a comprehensive review of all of the potential threats.

Via the web, Dr. Daniel Perez, University of Maryland, asked whether the potential of strains that resulted in past pandemics to affect humans would have been moderated if we had had the opportunity to sequence them. Fraser stated that understanding how a virus expands its host range from swine to humans requires a lot of information. The validation of the genotype to phenotype prediction tools really should address that question. Russell added that he did not think that having sequence information at the time of earlier pandemics would have forewarned of the emergence of those viruses, which again speaks to the incomplete nature of knowledge and the critical need for further work.

Another participant pointed out that there is probably a very large number of variables involved in understanding viral pathogenicity. Given the number of variables, is there much chance of doing anything useful? Russell and Fraser both agreed that this is a very complicated problem, which is why more experimental work is needed to help reduce the dimensionality. But what we currently know cannot help us very much in understanding what will occur in the next 5 years. However, science is an incremental process. The increases in understanding that have been achieved from the work that has been done so far have been helpful. In terms of translating directly into public health improvements, that is a pretty substantial leap to make. But saying we will not get there will not undermine science. Nevertheless, tools that can deal with perhaps thousands of genetic traits and phenotypes are needed. It is not about the mutations but rather about the function of the mutations. We could reach the state where we sufficiently understand the traits that a virus needs to adapt to humans and identify ways to test for those that are either independent of sequence or a metalevel of sequences.

Another participant made the point that had the 2009 pandemic strain been seen in animals instead of humans, it might have been falsely viewed as having low virulence and transmissibility and would have been discounted. Fraser agreed that the fact that our knowledge is incomplete right now creates a risk of discounting viruses that lack a certain number of substitutions when in fact we should be concerned about the risk.

Dr. Ron Fouchier, Erasmus MC, commented that he believes a lot is being asked of papers that were only published in 2012 and for which the follow-up work has been shut down twice for extended periods. This is work in which the phenotypes, not just the genotypes, are being studied. He agreed with Fraser that although he cannot yet predict phenotypes from genotypes, the assays produced by his work are being used to look at phenotypes in surveillance, which means a better job is already being done. He made a plea for more basic science to follow up on his work, which is still in the early stage. Fraser responded that the basic science is not under question. The question is: Should we be starting with experiments that have orders of magnitude higher risk than other work in the area?

Go to:

TREATMENT AND RESPONSE

Session 5, moderated by Baruch Fischhoff, consisted of a panel discussion with four speakers. Each panelist was given about 5 minutes and then the session was opened up for discussion.

The first speaker was Philip Dormitzer, who described how GoF research and the regulation around research affect the real-world case of trying to apply virology to a public health situation. For the purpose of his talk, Dormitzer described the chronology for the production and delivery of the 2009 H1N1 influenza pandemic vaccine, an "historical reminder," for which the response was the "fastest ever, but still came after the disease peaked" (Borse et al., 2013). In fact, an estimate published in *Emerging Infectious Diseases* (EID) showed that for every week of acceleration of vaccine supply, an additional 300,000 to 430,000 U.S. cases could have been prevented. Dormitzer explained that Novartis, in collaboration with the J. Craig Venter Institute (JCVI) and Synthetic Genomics Vaccines (SGVI), are now working together to establish a process for rapid generation of synthetic influenza viruses that includes GoF studies based on sequence motif data to guide the genetic assembly of the vaccine. For instance, the Novartis research team routinely screens for phenotypic traits of interest and can specifically remove or mutate strains with either polybasic cleavage sites in the hemagglutinins (HA) (found in highly pathogenic avian influenza viruses [HPAIV]) or neuraminidase (NA) gene markers of resistance. For that specific example, Dormitzer explained that the process from the identification of the relevant HA and NA sequences for the new influenza strain to the genetic identity confirmation of the vaccine virus lasted about 1 week. However, the next phase leading to the first large-scale clinical trial took months because of various well-intentioned regulations and policies to protect the food supply in the United States. Notably, because Novartis could not obtain a U.S. Department of Agriculture permit, this phase involved international research collaboration with Germany before taking the vaccine back to the United States, which unintentionally slowed down the human vaccine development. Under U.S. government regulations on select agents, vaccine development against HPAIV is counter-productive because "you can't really put an entire manufacturing facility under select agent conditions and still have a factory that can produce seasonal vaccines in an economically competitive way" and in a timely manner. Also, as Dormitzer pointed out, he "couldn't apply any of this [GoF research] technology." Therefore, if adaptation of vaccine virus to increase yield or more modern synthetic biology were captured by GoF regulations, then additional unintended impediments to timely vaccine supply could be created.

Next, Ralph Baric presented his view on the impact of GoF restrictions to the emerging coronavirus vaccine and therapeutic research. Baric started his talk by reiterating that no vaccine has been approved for MERS-CoV or SARS-CoV in the midst of an ongoing MERS-CoV outbreak. Baric explained how new restrictions reduce public health preparedness to respond to future SARS-like CoV outbreaks. He explained that the original vaccine target for the SARS-CoV outbreak 2002-2004 strain was 99 percent identical between human and civet (Ge et al., 2013). However, metagenomic sequencing showed that bat SARS-like CoV (SL-CoV) with 65 percent to 95 percent sequence homology, can constitute a large pool of strains with pandemic potential against which countermeasures need to be developed. To evaluate whether the existing vaccine and drugs work on these strains, Baric's team and others used two types of approaches.

The first was based on the production of CoV pseudotypes coated with virus spike-like proteins that can potentially engage the human angiotensin converting enzyme II (ACE2), which is the SARS-CoV cellular receptor molecule. This method constitutes a safe and ethical research alternative approach. Similarly, chimeric recombinant viruses that encode spike-like proteins as part of the virus particle can also be used. While studies using pseudotypes and structure-based prediction confirmed the existence of a bat SL-CoV that can infect human cells, only studies using GoF chimeric virus identified an additional bat SL-CoV as a potential threat. Baric noted that both bat SL-CoV were less virulent in a mouse model. Importantly for public health implications, data further showed that existing vaccine and human monoclonal antibody therapy failed to protect against these two newly identified bat SL-CoVs, leading Baric to point out that "we are vulnerable" to SL-CoV bat strains that currently exist in nature. The second part of Baric's talk described how robust animal models are essential for vaccine/drug design, safety testing, and performance outcomes. He explained that SARS-CoV replicates poorly in mice (Frieman et al., 2012) and although his team and Subbarao's lab have developed mouse-adapted strains, the in vivo correlates of infection vary widely depending on the model used. For example, he described some collaborative work done on inbred and outbred mice demonstrating that in some cases the vaccine could have caused increased mortality in some individuals and emphasized the need for better animal models for SARS-CoV vaccine research. In the case of MERS-CoV, the epidemic is ongoing and no robust animal model exists because routine GOF studies, including passage in small animal models, have failed. Baric called for an immediate lifting of the restrictions on MERS-CoV research on animal model development. This was echoed by other participants during the final discussion. For example, Peter Hale of the Foundation for Vaccine Research stated that he thought the inclusion of the coronaviruses in the "pause" was "muddying the waters" and that he did not detect any enthusiasm among SARS and MERS investigators to increase their transmissibility. This point was also made strongly during the discussion following the session.

The next speaker was Dr. Jerry Weir from the Food and Drug Administration's Center for Biologics Evaluation and Research, whose team participates in the selection of strains for the yearly influenza vaccines and regulates viral vaccines to ensure that they are safe and efficacious for human use. Weir offered some comments about how the regulatory process views some of the experiments and techniques addressed by the symposium speakers. He stated that there are actually not very many, if any, regulatory issues associated with the type of virus manipulations that were under discussion (i.e., improved types of seed development, reverse genetics, manipulation of virus genomes to improve vaccine virus stability or performance). Manufacturers already licensed can submit a supplement to the license that is evaluated for using a fairly standard process. In lieu of giving examples of how GoF research can influence a process, Weir mentioned a few challenges that still remain in vaccine development for the influenza virus. In general, for the seasonal strain selection and the preparation of pandemic vaccine strains, the major challenge is the existence of very large gaps in our knowledge of how genotype sequences relate to phenotypic changes. Weir stated that strain prediction and selection remain a "guessing game … for which improvements are desperately needed." In addition, for other factors such as transmissibility or virulence, a lot is not known and improvements are also needed there. To complicate the matter, the incorporation of four, instead of three influenza strains in the seasonal vaccine is a challenge every year for the different players in the global community that pick the vaccine strains as well as the manufacturers who need to deliver the vaccines in a timely manner. For them the yields of vaccine viruses need to be improved with the challenge of limiting factors such as poorly growing strains among the four chosen. In his view, Weir believes that, as broadly defined, "GoF studies have had an enormous influence on how we develop vaccines over the years … and can help improve the process with the challenges that we still face."

The final speaker was Mark Denison, who explained his view of GoF studies in MERS-CoV and SARS-CoV countermeasure development and how oversight or regulation might be limiting. Denison reminded the audience about the basic research and ongoing challenges that remain in the development of therapeutics to SARS and MERS-CoVs, emphasizing, like other speakers, the need for in vivo and in vitro models to identify common mechanisms and determinants of resistance. He then moved to a case study involving GoF research and asked the audience whether they would consider giving or taking "a live vaccine with a virus that has an engineered increased mutation rate," for which only a few people raised their hands. The question was an introduction to a series of studies showing that CoVs, contrary to other viruses, express a proofreading exonuclease (ExoN) normally only found in bacteria and eukaryotes. When this ExoN was inactivated, the CoV mutation rate was increased by 20-fold. Normally, mutations allow tremendous variation in viral populations and presumably increase adaptation, fitness, virulence, and therefore public health risks. However, GoF studies demonstrated that SARS-CoV with the inactivated ExoN were less fit, attenuated in a mouse model of lethal

SARS-CoV, could not compete with the wild-type virus, and could therefore be used as a target for therapeutics development. This work was also adapted to other RNA viruses with encouraging results. Denison used this case study to reflect on the implications of new regulations and guidelines if he wanted to create a mutated strain of a virus and test it in an animal model. In conclusion, Denison stated that he believes that because assumptions are usually wrong, GoF research that includes "passage for adaptation and resistance in in vitro and animal models are essential components of therapeutics development" and that to his knowledge no bioinformatics or predictive safer alternative approaches are effective to develop new countermeasures.

Following the panel member's presentations, there was discussion with the audience. Fraser asked Dormitzer how he would propose to reconcile, practically, the need to conduct very dangerous research without casting the net too wide. Dormitzer responded that what is first needed is a very clear and limited definition of the sorts of research that require particular attention. As Relman discussed, experiments that combine increased transmissibility, virulence, and and lack available countermeasures are very concerning. But we have to make sure that the definitions are not too broad so that they do not capture a lot of other work. Second, there needs to be a distinction between the highly diverse work performed for basic research and the much more restricted, but more urgent, work needed for vaccine development. A classic example is H5N1 vaccine development. There have been at least 26 H5N1 strains that have been attenuated all in the same way. But for the 27th one, the often months-long routine must be goone through again. We need clearly established, well-defined pathways to get vaccines quickly and not encumber the process with regulations.

Relman also stated that he does not think that there is a major question about the value of MERS and SARS research, even that research that currently falls under the rubric of GoF. Restrictions do, in fact, hamper the quest to develop countermeasures, etc. What he thinks is a more interesting question is whether there is a very discreet and specific set of experiments with MERS and SARS that you might not want to see undertaken. For example, would it be appropriate to deliberately start with a highly virulent human isolate of MERS and then attempt to add to that much enhanced human-to-human transmissibility by the respiratory route? Baric responded that he did not know of anyone doing transmissibility studies with the human coronaviruses. Unlike flu, there are currently no small animal models suitable for MERS or SARS transmissibility assays. This is mostly due to receptor incompatibility between the human and any small animal models. Optimization assays to enhance virus transmissibility between ferrets, for instance, would probably decrease the ability of that modified virus to bind to the human ACE2 receptor. Relman reformulated the question to include the possibility of using transgenic ferrets with the human receptor, but Baric explained that the human receptor itself is not sufficient and that other proteins are essential for viral transmissibility and, therefore, the results in transgenic models would not be predictable.

Denison added that nobody would have as a goal or would support trying to increase virulence and transmissibility of MERS or SARS. That is why he recommends the use of a case-based approach that looks at how we really do science. Denison shared his approach when sending a proposal through study sessions or review process at a funding institution. For him, instead of trying to define "boundaries of absolute," the real question should always be, "What is the best approach to answer that question?" Then, depending on the stage of the review process, the response should be iterative to be adequately addressed.

Inglesby asked Dormitzer whether the annual process of production of flu vaccine relies on research using highly transmissible and highly virulent strains. Dormitzer responded that this is not the case and that the goal is quite opposite—to take a strain found in nature and transform it into something that can be manufactured efficiently by increasing its growth rate in cell culture or eggs. Inglesby then asked whether virulence and transmissibility are traits that can be distinguished from increased growth capability. Dormitzer stated that there is precedent that shows that adapting viruses to grow better in cell culture does not, in general, increase their virulence or transmissibility, whereas passaging from animal to animal often does. He stated that we also need to distinguish between two things: the need for very rapid production of new antigenic variants, which should start on the day it is found that there is a new variant causing disease, and the development of the vaccine backbone, which could be used in multiple variants and which you do not want to take forever. It is not the same issue when facing an emergency.

Dr. Simon Wain-Hobson, Institut Pasteur, echoed Denison's presentation by citing work done on polio by John Holland 15 years ago that showed that when chemical mutagenesis is combined with a rapidly evolving RNA virus such as polio,

the fitness of the virus goes down. Several members of the panel agreed. However, Denison raised the issue of perception in the current environment and under the current policy circumstances. Such proposals might not necessarily be vetted even though most of the time we can not know the answers until the experiments are conducted.

Another questioner from the webcast asked Dormitzer whether, in his opinion, GoF research is essential for future development of intervention strategies against various pathogens. Dormitzer responded that he thinks it depends on whether you are talking about the short- or long-term. He stated that GoF research is not going to help pick next year's flu vaccine, but if one is making viruses for use in manufacturing and a certain genetic motif that correlated with high transmissibility is known, then one could make sure that the motif is not included in the vaccine strain. GoF research has utility for such purposes. The other thing is that vaccine manufacturers are increasingly figuring out how to take genetic data and use it to predict what they want to make. That would be a genuine utility if it could be done. The question is whether we can do that kind of science in a way that does not create more problems than it solves. There is potential for GoF research to improve vaccine production, but it is not today except for limited instances; it has long-term potential for this purpose as long as the work can be done without inordinate risk. Denison asked whether any "bad" GoF experiments were performed to discover the polybasic cleavage site associated with high virulence. Dormitzer listed what is believed to have led to this discovery, including studies on correlations between the presence of these sites and clinical observation of virulence in birds; discovery of plausible mechanisms looking at cleavage proteins expressed in different cells; and loss-of-function and GoF studies to make sure that the gene identified is the correct one. Denison's point was that a series of experiment led to that conclusion.

It was clear, however, that there is a substantial disagreement over the value of GoF research for vaccine development. Lamb, in a later session (Session 8), stated that he thought we should modify the mantra that GoF research is useful for vaccine and antiviral drug development. He thinks that this point is overused and oversold. Hale also commented during the final discussion that he agreed with Lamb, we do need to modify the mantra that this research will help develop vaccines and antivirals. He said that he and his Foundation fully endorse that sentiment. It is an argument that is made over and over again without evidence to substantiate it. He believes that in terms of development of better vaccines, GoF research has little or no benefit, and if there is any benefit, then it is tiny and way down the road. In the meantime, he said, it is not worth the risk and there are other priorities.

Dormitzer responded to the latter comment and acknowledged that the community of people who make vaccines is divided just as much of the symposium audience was divided. He stated that the basis for that division is informative. Flu vaccines today are still made by very, very old techniques. One looks at what is spreading, sees if it has changed, and then picks the strain. There is not a lot of basic science in this; rather it is 1960s science. In 2009 we were not able to get the H1N1 vaccine out until after the outbreak had peaked, and many people have commented that the current flu vaccines, although somewhat effective, are not good enough. A lot of people who work on vaccines think we need to do things better. One way to do things better is to take advantage of the available information, particularly sequence-based information, so we can do things faster and make vaccines better. Information from GoF research can contribute to identifying risks earlier so countermeasures can be taken earlier. Dormitzer said he does not think it is the case that GoF research is essential to the current vaccine system as it is generally practiced today, but it is not useless. It is clearly part of the trend to understand and predict what can be done better and to help respond quickly. That does not mean it is open season to do what you want and forget the risks. A balance is needed. But he was firm in his statement that the vaccine producers are not universally of the opinion that there is no use for GoF research.

Koblentz asked whether the coronavirus researchers had a sense and could comment on why MERS and SARS were included in the "pause" on GoF along with influenza. Denison believes that, despite the circumstances, the inclusion of SARS- and MERS-CoV in the "pause" demonstrates that this is not about one virus but more about the issue of how we address critical questions in science and what constitutes appropriate review and safety among the different research institutions. He believes that whatever the question asked, whether about replication or virulence and transmissibility, the science should be the same and should follow an iterative process that incorporates risks, milestones, and points to change along the way.

As a follow-up from Relman's question on transmissibility in MERS and SARS animal models, Koblentz asked Baric to clarify which set of experiments he would use to study transmissibility. Baric explained that many variables are needed

to make a model to enhance transmissibility, but if he had the perfect model to do these experiments he would not do them. Later during the discussion, prompted by Inglesby, Baric added that because the CoV interaction barriers are species specific, the only real absolute model that could be used would be human, so he certainly would not do the experiment.

Fraser asked Denison to clarify what he meant when he said that no one would want to increase the pathogenesis or transmissibility of MERS and, therefore, that the regulation should not apply to MERS and SARS research, especially because this is what the debate is about. Denison explained that he thinks that increasing transmissibility of human coronaviruses is not a goal. He then described the importance of research on wild-type or genetically modified animal models or cell cultures to understand determinants of pathogenesis or virulence factors. No one has the goal to increase these characteristics, but researchers need to be able to study the virus or they would need to rely on epidemiology and surveillance, which are not adequate to answer the question. Denison also stated that to his knowledge there is no other approach to develop countermeasures and vaccines.

Richard Roberts, New England Biolabs, asked whether experiments on dangerous traits that exist in highly pathogenic and virulent strains could also be done on strains that have already been incapacitated in some way. Denison agreed that on a case-by-case basis, if it is possible, then a safer approach is always preferred, but that it depends on the genetic background of the strain of interest. As an example, Denison explained that sometimes a certain type of loss- or gain-of-function experiment is undertaken on BSL-2 strains that are 90 percent identical to more virulent strains, but that the small genetic background differences and therefore structure can greatly influence the outcome of the experiment. When one has strains that are not genetically identical or from the same clade, it may not be possible to make the right determination without doing the experiments.

A participant from the Department of State noted that although there may be ways to do the research in a safer manner, Denison had just argued that in a competitive environment the research question should be answered in the best and most direct way to get funding. The participant wondered whether, in this competitive context, a researcher would prefer the safest, but perhaps more indirect, option assuming it would get at the question. Denison commented that sometimes there are safer options such as when he used a mouse model for hepatitis virus to identify determinant proteins such as those for proofreading. This approach is of public health importance because it proves that certain mechanisms might be a useful target across multiple strains, including those we have not yet tested, such as the basic cleavage site. Returning to his earlier comment about the funding, Denison explained that professors not only try to educate students to do the best science in the best way, but also ask them about finding alternatives that will eventually answer the question in a less direct way. Dormitzer added that although one may get NIH funding through a grant that incorporates safety considerations, institutional safety boards and questionnaires about dual use research of concern are procedures already in place to make sure it is not only the most direct way to a scientific answer taken, but also that safety is considered.

Each of the panel members was then given an opportunity for closing remarks. Dormitzer's closing remarks were that he believes that there is long-term potential in GoF research. He believes that we must be very careful with any sort of restrictions or regulations to make sure we do not inadvertently capture a lot of work that is not only good for basic science, but also a core part of the public health response. He stated that as a practitioner of vaccine development, he has realized that there really are road blocks that were never intended by the people who drafted the restrictions.

Baric agreed with those comments and affirmed the importance of reverse genetics and GoF research in understanding viral pathogenesis as well as vaccine and therapeutic design. NIH should be very careful about delineating the boundaries of the restrictions to be placed on the research community because there could be dire consequences if these restrictions are too broad. Weir affirmed one of his earlier points: if we had great vaccines for all of these agents, we might be having a different discussion, but the fact is that we do not.

Denison closed by proposing an iterative process whereby scientists do a review along the way. For critical pathogens of high human consequence there should be a mechanism that allows for a case-based, iterative approach that identifies problems along the way. Investigators need to have their research supported and be allowed to integrate best practices when doing GoF research.

Bookshelf ID: NBK285583

From: Peter Daszak [b6]
Sent: 8/24/2021 12:40:19 AM
To: Morens, David (NIH/NIAID) [E] [b6]; Keusch, Jerry [b6]; Robert Kessler [b6]; Roberts, Rich [b6]; Hotez, Peter Jay [b6]
Subject: Under Embargo - Commentary in Nature Wednesday morning
Attachments: Koopmans et al. Comment Covid Origins Nature 2021.pdf

Importance: High

I'm attaching a commentary that will come out on Wednesday in Nature. It was originally written as a response to the WHO DG deciding to bail on the WHO team and call for a new structure and a focus on the lab leak/audit. We've watered it down so it's not too political, and focuses on the fact that this has stalled the process. The key messages from our point of view are that:

1. the search for the origins is important and needs to continue
2. since our report, we feel that most attention has gone to debates regarding likelihood of a lab leak, at the cost of progress in other areas
3. we should all be concerned that time passing - in part owing to these discussions – and this could close the window of opportunity for some critical studies
4. there are critical issues to deal with that are laid out in the report as recommendations for Phase 2: tracking back from the market, following new leads from the recent paper on mammals in the market, representative wild animal and farmed wild animal surveys, and comparative serosurveys in all regions where there has been evidence of early circulation.
5. the lab audit - as added- will need to be developed to define questions. The smallpox audit example cited by WHO in their press addresses biosafety and biosecurity for that pathogen, but would not necessarily help identify evidence for a lab leak. Developing those studies, and agreeing them with China may take of lot of time and that these should not lead to further delays for the other recommended studies

I'm still trying to stay out of publicity as much as possible, so will be avoiding reporters on this one.

Cheers,

Peter

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From: Peter Daszak [b6]
Sent: Monday, August 23, 2021 8:35 PM
To: 'Morens, David (NIH/NIAID) [E]' [b6] 'Keusch, Jerry ([b6])' [b6]; Robert Kessler [b6]; 'Roberts, Rich' [b6]
Subject: Francis Collins on CNBC today

Hello everyone - Not looking forward to the publicity this week with the Intel report coming out sometime soon, but wanted to share a couple of things.

First – here's an interview by Francis Collins on Squawkbox CNBC that makes him come over like a wet lettuce. He goes one way then the other, making sure he sounds somewhat anti-China (they could have been doing mysterious things), but makes it clear NIH didn't fund Gain of Function there.

It's the definition of flip-flopping I guess. Maybe he genuinely believes China were up to something. In any case, it feels like he basically couldn't care less about the organization in the middle (EcoHealth) that's being batted around like a table tennis ball…
The URL is here: https://www.cnbc.com/2021/08/23/covid-origin-nih-director-doesnt-rule-out-that-virus-could-have-leaked-from-lab.html

NIH director says Covid likely came from nature, but doesn't rule out it could have escaped from lab

PUBLISHED MON, AUG 23 202112:53 PM EDTUPDATED MON, AUG 23 20211:08 PM EDT
Rich Mendez@RICHMENDEZCNBC

KEY POINTS

President Joe Biden gave the U.S. intelligence community 90 days to investigate Covid's origins and report the findings, which are due Tuesday.

Through a grant to non-profit EcoHealth Alliance, the NIH funded research at the Wuhan Institute of Virology to study how bat viruses could infect humans.

Collins said the research didn't meet the technical definition of so-called gain-of-function research.

The director of the National Institutes of Health said Monday it appears Covid-19 originated from an animal, but he didn't rule out the possibility that scientists at the Wuhan Institute of Virology were secretly studying it and that it could have leaked out from there.

It's still unknown if the virus leaked out of a Wuhan lab, NIH director Dr. Francis Collins said Monday in an interview on CNBC's "Squawk Box," adding that the World Health Organization's investigation into the origin of the coronavirus has gone "backwards."

"The vast evidence from other perspectives says no, this was a naturally occurring virus," Collins said. "Not to say that it could not have been under study secretly at the Wuhan Institute of Virology and got out of there, we don't know about that. But the virus itself does not have the earmarks of having been created intentionally by human work."

The WHO investigation has been made harder by China's refusal to participate, says Collins.

"I think China basically refused to consider another WHO investigation and just said 'nope not interested'," Collins told CNBC's Squawk Box.

"Wouldn't it be good if they'd actually open up their lab books and let us know what they were actually doing there and find out more about those cases of people who got sick in November of 2019 about which we really don't know enough," Collins said.

U.S. intelligence reports first reported by the Wall Street Journal indicated that in November 2019, three workers at the Wuhan Institute of Virology fell ill with symptoms similar to those seen in Covid-19 infections, a report that China said was "completely untrue."

About three months ago, President Joe Biden initiated an investigation of his own and gave his intelligence community 90 days to further the investigation the virus' origins and report the findings. The deadline is Tuesday.

"It will be an interesting week because tomorrow is the day of the 90-day deadline that President Biden set for the intelligence community to do all their poking around that they could to see if they could come up with anymore insight as to how this virus got started in China," Collins said.

Most of the information gathered will likely remain classified, but some information from the report will be released, according to Collins.

"We don't know what they're going to come up with either, but we're intensely interested," Collins said.

Collins also weighed in on the debate over whether or not the U.S. funded so-called gain-of-function research at the Wuhan lab, a debate that Republican Sen. Rand Paul of Kentucky and medical advisor to the president, Dr. Anthony Fauci, have engaged in time

and time again. Gain-of-function research is when scientists take a pathogen and make it more contagious, deadly or both to study how to combat it.

“The kind of gain-of-function research that’s under very careful scrutiny is when you take a pathogen for humans, and you do something with it that would enhance its virulence or its transmissibility,” Collins said. “They were not studying a pathogen that was a pathogen for humans, these are bat viruses.”

Some of the research at the Wuhan Institute of Virology that was funded, in part, by the NIH through a grant to non-profit EcoHealth Alliance studied how bat viruses could infect humans.

“So by the strict definition, and this was look at exquisitely carefully by all the reviewers of that research in anticipation that this might come up, was that this did not meet the official description of what’s called gain-of-function research that requires oversight,” Collins said. “I know this has gotten lots of attention, but I think it’s way out of place.”

Cheers,

Peter

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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From: Morens, David (NIH/NIAID) [E] b6
Sent: Monday, August 23, 2021 5:33 PM
To: Peter Daszak (b6) b6; Keusch, Jerry (b6) b6; Kessler, Robert (b6) b6
Subject: FW: Vice: Why China Is Struggling to Make the Lab Leak Theory Go Away

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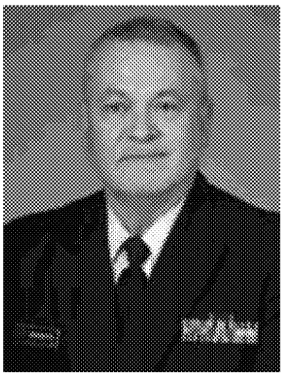

From: Folkers, Greg (NIH/NIAID) [E] b6
Sent: Sunday, August 22, 2021 12:29 AM
Subject: Vice: Why China Is Struggling to Make the Lab Leak Theory Go Away

Why China Is Struggling to Make the Lab Leak Theory Go Away

U.S. spy agencies are about to report on COVID-19's origins, but don't hold your breath.

by Alan Wong

by Viola Zhou
August 20, 2021, 9:38am

Robert Redfield has a lot of questions. The virologist and former director of the U.S. Centers for Disease Control and Prevention wants to know what happened at the Wuhan Institute of Virology, especially in the months before the emergence of COVID-19 in the same city. But China's answers didn't satisfy him.

"On Sept. 12, 2019, coronavirus bat sequences were deleted from the institute's database. Why? It changed the security protocols for the lab. Why? It put out requests for more than $600 million for a new ventilation system. What prompted this new need?"

Redfield, who believes that the coronavirus escaped from the lab in Wuhan, asked those questions in the *Wall Street Journal* on Sunday, alluding to the possibility that something bad happened at the facility as early as September that year and caused a pandemic that has killed more than 4 million people worldwide. To bolster this view, he said a Harvard study of satellite images revealed a shutdown of traffic around the Wuhan lab around that time and that hospital parking lots in the city were filling up—signs, perhaps, of a lab accident and a subsequent surge in sick people.

But almost all of those insinuations are disputed, inaccurate, or just plain wrong.

The opinion article offers a stark illustration of the limits of circumstantial evidence as the search for the origins of COVID-19 enters a contentious new phase.

U.S. spy agencies are preparing to release a report on their findings on whether the pandemic started from human contact with an infected animal or a laboratory accident in China. The report is expected no later than next week, after President Joe Biden in May gave the U.S. intelligence community a 90-day deadline to further collect and analyze information that could "bring us closer to a definitive conclusion" on the origins of COVID-19.

But China is not keen to cooperate. Further muddling the search is Beijing's renewed push of an unsubstantiated, alternative theory that the virus could have originated in a U.S. army lab at Fort Detrick, Maryland. The move has only fueled suspicions that the Chinese government is hiding something.

Unless U.S. spies uncovered substantial evidence—such as proof that the Wuhan lab possessed the virus that caused COVID-19 or evidence that it created the virus—the debate on the pathogen's origins is likely to persist.

Redfield co-authored the *Journal* article with Marc Siegel, a physician and *Fox News* contributor who last March said the coronavirus was no worse than the flu. It was riddled with mistakes.

For example, the planned ventilation system upgrade at the Wuhan Institute of Virology cost about $600,000, not $600 million as the authors stated. The figure was corrected on Friday, a day after VICE World News emailed questions to the *Journal*'s opinion desk. That number came from a report by Republicans that exaggerated the amounts of several other projects by orders of magnitude and has been cited in several other prominent news outlets.

The Trump-appointed former director of the CDC apparently also misattributed the findings of a military contractor's report to Harvard. The Harvard study he links to analyzed satellite images of hospital parking lots in Wuhan, but it did not once mention the Wuhan Institute of Virology. It was also criticized for its poor dataset, abuse of statistical methods, and mistranslation.

The analysis of traffic outside the Wuhan institute used commercial satellite imagery and phone location data to conclude that traffic was unusually thin around the Wuhan institute and was the result of containment efforts following a hazardous event. But the report's key assertions were found to be false as early as June last year.

These are just a few examples, from one article, showing the challenges of investigating the origins of the coronavirus without being in China and without the country's full cooperation.

The closest thing to a field study the world has seen was the World Health Organization (WHO) trip to China early this year, but the global health body has complained about not being able to access the complete raw data from the early COVID-19 patients that could give researchers insights into how the virus emerged.

Last month, the WHO chief urged Beijing to share the data, but Chinese officials said the information could not be disclosed due to patients' privacy. Some scientists are not convinced by the argument, citing the possibility of disclosing the data while keeping the patients' anonymous.

Beijing's obsession with a theory that the coronavirus could have been brought into China through frozen food imports has also raised doubts. Officials have kept calling for more research into such potential cold-chain transmission, although few scientists abroad have found it credible enough to justify further investigation.

"In my opinion, it's even less likely than lab origin," Angela Rasmussen, a virologist at the University of Saskatchewan in Canada, told VICE World News. Rasmussen, who has argued in favor of a natural origin of the coronavirus, said the Chinese government might be trying to distract people from the wildlife trade that could have led to a virus zoonotic spillover.

Scientists say only greater transparency will help Chinese authorities fend off all these suspicions. "We are being asked to take their words for it, without seeing any data," said Alina Chan, a biologist at the Broad Institute in Cambridge, Massachusetts, who has promoted the lab leak hypothesis. Chan told VICE World News she would like to see all of the sequences of the pathogens that were processed at the Wuhan lab. If the data could not be made public, she said, they should at least be reviewed by an international team of scientists.

"This situation is setting precedents for how future outbreaks are tracked," she said. "If every single country does this, and refuses to let international investigators check where the virus came from, we would just be facing a future where viruses are just exploding everywhere, and we are just getting a new pandemic every five or ten years."

Some other scientists still maintain that the lab leak theory is unlikely, in contrast with what they have called a "substantial body of scientific evidence" supporting a natural origin for the coronavirus, according to a peer-reviewed paper published in *Cell* this week.

Still, with few new data points to inform the origins probe, scientists on both sides of the debate have called for greater transparency.

WHO Director-General Tedros Adhanom Ghebreyesus in July said the lack of raw data on the early days of the outbreak was hampering the investigations into the origin of the virus and urged China to be more transparent. Tedros suggested further studies into Chinese laboratories in the next phase of studies.

But the Chinese government would not feel comfortable with this degree of transparency. The Communist Party leadership is used to conducting investigations and making decisions behind closed doors, and sees the call for openness as a political threat.

"That is not atypical in China's crisis management," Yanzhong Huang, a senior fellow for global health at the Council on Foreign Relations, told VICE World News. "The U.S. could push for more transparency, but they fail to recognize that the lack of transparency itself is part of the authoritarian governance in the country."

This mindset could hurt China's reputation—the pandemic is not a small crisis but one that has upended almost everyone's life. "Even if the virus is caused by a natural spillover event," Huang said, "when you don't show transparency, when you are perceived as unwilling to share the data, people naturally will think you have something to hide."

The Chinese government has remained intransigent to the mounting calls for more transparency.

At the press conference last month, Chinese officials said they were "shocked" to hear about WHO's proposal for fresh audits into Chinese labs, adding the suggestion indicated "disrespect for common sense and an arrogant attitude toward science."

The same month, state media quoted a Facebook post by a self-claimed Swiss biologist named Wilson Edwards as saying that researchers faced intimidation from the U.S. for supporting the WHO-China origin-tracing study. The Swiss embassy said no such person exists.

It's unclear whether the U.S. intelligence probe, which was condemned by Chinese state media as a "political witch-hunt," would yield anything more than circumstantial evidence.

By the time a preliminary report was drafted, the intelligence community was still divided over the lab leak theory and the natural origin one, CNN reported this month. The outlet cited a source as saying that the draft contained "nothing too earth shattering."

In September 2019, the Wuhan Institute of Virology shut off public access to its database, which holds thousands of genetic sequences of bat coronaviruses it studied.

Shi Zhengli, director of the Center for Emerging Infectious Diseases at the institute, said the online database was shut down after cyberattacks—believe it or not, that's the answer to ex-CDC director Robert Redfield's first question. But almost two years later, the database remains offline. It's no wonder that people are asking questions.

Follow Alan Wong and Viola Zhou on Twitter.

Comment

ALY SONG/REUTERS/ALAMY

The World Health Organization assembled a team of staff and independent experts tasked with understanding the origins of SARS-CoV-2.

Origins of SARS-CoV-2: window is closing for key scientific studies

Marion Koopmans, Peter Daszak, Vladimir G. Dedkov, Dominic E. Dwyer, Elmoubasher Farag, Thea K. Fischer, David T. S. Hayman, Fabian Leendertz, Ken Maeda, Hung Nguyen-Viet & John Watson

Authors of the March WHO report into how COVID-19 emerged warn that further delay makes crucial inquiry biologically difficult.

Our group was convened by the World Health Organization (WHO) in October 2020. We have been the designated independent international members of a joint WHO–China team tasked with understanding the origins of SARS-CoV-2. Our report was published this March[1]. It was meant to be the first step in a process that has stalled. Here we summarize the scientific process so far, and call for action to fast-track the follow-up scientific work required to identify how COVID-19 emerged, which we set out in this article.

The window of opportunity for conducting this crucial inquiry is closing fast: any delay will render some of the studies biologically impossible. Understanding the origins of a devastating pandemic is a global priority, grounded in science.

The mandate

We, all the members of the international expert team, each submitted detailed, confidential statements to the WHO on potential

conflicts of interest, including funding, collaborative studies, public statements and other issues around the origins of COVID-19 that could be perceived as conflicts. After the WHO had reviewed these, team members were appointed in their individual capacity, not as representatives of their employers.

So far, our mission has been guided by terms of reference agreed between the WHO and China in 2020, before our involvement[1]. These terms tasked us with making a detailed reconstruction of the early phase of the pandemic, beginning in Wuhan, China, where the first known cases were reported. Our mandate was to conduct a collaborative study with leading scientists in China to review data they had generated on the basis of initial questions from the WHO. We refined the generic list of questions described in the mandate into a detailed workplan described in the mission report[1] (see also Annex A; go.nature.com/3k26jzx).

The workplan specified eight items: specific retrospective studies detailing the profile of respiratory illness in the general community and hospitalized people in Wuhan and Hubei in the second half of 2019; a review of patient files for 76,000 cases in the same time period that had been notified by 233 Wuhan health centres; a review of death certificates and analysis of those data for possible clusters; and a detailed reconstruction of the investigation into the early outbreak, combining all data and findings from the various groups involved in human, animal and environmental studies (a One Health approach; see go.nature.com/3jy7ekh). The other four items were: extensive mapping and traceback of the supply chain of products sold at the Huanan seafood market in Wuhan; testing of a wide range of livestock, wildlife, pets and zoo animals for evidence of infection with SARS-CoV-2; analysis of published and unpublished viral genomic data and linking them with metadata for reconstruction of initial clusters; and a review of relevant literature related to the origins mission.

The possibility of a laboratory origin for the virus's introduction into the local human population – what has come to be called the lab-leak hypothesis – was not part of the WHO's original terms of reference for the team.

The mission

This January, we undertook a 28-day mission to Wuhan to interview clinical, laboratory and public-health professionals and visit institutions involved in the early epidemic response and subsequent investigations. Our work was supported by a team of staff from the WHO China office and from WHO headquarters in Geneva, Switzerland; staff from the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE); and a WHO-appointed team leader[1]. The huge burden of preparatory work was shouldered by the team in China, including more than 1,000 health-care professionals who collected, analysed, presented and discussed data and study outcomes during our joint mission.

WEI LIANG/CHINA NEWS SERVICE/GETTY

Officials collect COVID-19 test samples in a fresh market in China's Shanxi province in January.

Scientific discussions between the international and Chinese teams during this mission were lively. Large amounts of information were exchanged on the basis of the work carried out. It took days of discussion to develop recommendations on essential further work and ongoing data sharing. We drafted a model of the potential 'pathways of emergence' to structure our thoughts. We listed current evidence for and against these pathways (see Fig. 1 of ref. 1).

> "We had limited time on the ground in Wuhan and a limited mandate."

We found the laboratory origin hypothesis too important to ignore, so brought it into the discussions with our Chinese counterparts. And we included it as one of the hypotheses for SARS-CoV-2 origin in our report.

We had limited time on the ground in Wuhan and a limited mandate. So we prioritized understanding the role of labs in the early days of the epidemic, the overall lab biosafety procedures and potential staff illness or absenteeism owing to respiratory disease in the late part of 2019. We spoke to the leadership and staff at the three Wuhan labs handling coronaviruses: the Wuhan Institute of Virology, the Chinese Center for Disease Control and Prevention (CDC) in Wuhan, and the Hubei provincial CDC. We reviewed published work from these labs to assess their scientific history of working with coronaviruses related to severe acute respiratory syndrome (SARS).

The Chinese team was and still is reluctant to share raw data (for instance, on the 174 cases identified in December 2019), citing concerns over patient confidentiality. Access to data on these cases was not specified in the mandate, although the WHO had demanded it during the investigation, and has done so since. The legal and possible other barriers could not be addressed in the short time frame of our visit. Also, by then, it was clear that the 174 cases were not likely to be the earliest ones, so we considered them less urgent for understanding origins.

It was therefore agreed that a second phase of studies would address these concerns and review these data.

The report

In our joint report[1], members of both teams concluded unanimously that there was clear evidence of widespread SARS-CoV-2

GETTY

A woman pushes a cart at the closed wholesale seafood market in Wuhan, China, last January.

circulation in Wuhan during December 2019. We reported evidence for earlier emergence but reached no resolution on when, where and how that occurred. We concluded that the Huanan seafood market had a significant role in the early part of the pandemic, and that there were credible links to wild-animal markets to follow up. We agreed that the earliest cases of COVID-19 had probably been missed, as is common for outbreaks of new diseases[2].

Our joint report summarized the evidence base that was generated during this first phase of origin tracing. It concluded that there was no definitive proof for or against any of the four proposed pathways: direct zoonotic introduction (through a spillover from wild animals) and three indirect routes of introduction (see Fig. 1 of ref. 1). These three are: zoonotic infection from handling infected farmed animals; zoonotic introduction through the consumption of contaminated food or food from infected animals; or introduction through escape from a laboratory working with animal viruses. The report noted that we considered direct introduction or indirect zoonotic introduction through an intermediate host the most plausible.

As laid out in our terms of reference, this initial study was not expected to provide definitive answers to the origin of SARS-CoV-2. Rather, phase 1 was always intended to form the foundation of a longer process of scientific investigation that could last for months or years. Therefore, the report put forward recommendations for phase 2 studies that would follow the evidence and trace back further along the most likely pathways. As a joint WHO–China study report, these recommendations were agreed on by members of both the international and the Chinese team. The report also stated that this assessment could be revised if new evidence became available.

The response

Before the report was released, formal statements to the WHO from some governments were circulated in February, with three contentions: that China had not shared data adequately; that we had paid insufficient attention to the lab-leak hypothesis; and that our scientific conclusions were influenced by China's political stance regarding transmission through the food chain.

Since its release, our report has received extensive coverage in the popular and scientific press and on social media. Much of this has focused on how we conducted the work, and has critiqued us, our methods and results. Five months on, criticisms of the WHO–China joint study continue to emerge.

When asked, our team has emphasized that much new information was shared by the Chinese team as a result of the agreed studies, and that even more was shared as part of the iterative process between the international and Chinese teams.

Our critics have also suggested that the report dismisses the possibility of a lab leak. A laboratory origin hypothesis is presented in the pathway model in Figure 5 on page 119 of the report; we explicitly state in the report that it is possible. We held frank discussions with key scientists in the relevant Wuhan institutions – a line of inquiry that exceeded our original mandate. When we reviewed the responses to our questions on this issue, and all other available data, we found no evidence for leads to follow up; we reported this fact.

In our report, we state that if evidence supporting any of the hypotheses becomes known following publication, phase 2 studies should carefully examine this. For instance, we described that there was evidence of the presence of live animals in the market at the end of December 2019, but that the data presented to the team did not show definitive evidence of live mammals. This evidence came to light after publication[3] (as we discuss in more detail later in this article).

Another criticism was that the potential for introduction of SARS-CoV-2 through frozen food was included owing to pressure from China. The report addressed this hypothesis for three reasons: analysis showed that frozen food imported from all over the world was sold at the Wuhan market, including frozen wild-animal meat; foodborne viral-disease outbreaks are widely documented, including occasionally from frozen foods; and SARS-CoV-2 can remain infectious when frozen[4]. Therefore, the team felt it could not rule out introduction from undercooked meat from infected animals.

Some of the public discourse around the report probably originates from miscommunication and misunderstanding about the nature of the work. Although the published report correctly calls it a joint study to reflect what was laid out in the World Health Assembly resolution and terms of reference, it was publicly called an investigation by journalists, by representatives from some member states and, on occasion, by representatives of the WHO. This might have led to expectations that

the report would provide watertight evidence based on formal audits of the institutes involved in the studies.

New data

There have been calls from scientists for further investigation of the lab-leak hypothesis[5]. And there has been a wave of media items that give equivalence to the weight of evidence for a lab leak and for emergence through an intermediate host – an equivalence that the currently available data do not support, in our view.

The arguments and data for a zoonotic spillover event were summarized in a review published as a July preprint by a group of scientists who were not part of the international team[6]. That review includes new data released since the report, on SARS-CoV-2-related coronaviruses in bats in China's Yunnan province[7,8] and an inventory of live mammals for sale in Wuhan markets up until November 2019, some of which could have theoretically been able to harbour SARS-related coronaviruses[3]. This inventory, compiled by scientists from the United Kingdom, Canada and China, would have been welcomed by the team had it been available earlier; it needs to be taken up in the phase 2 studies.

In June, a preprint[9] was published analysing genomic data that had been deleted after March 2020 from the database of the US National Center for Biotechnology Information at the request of the scientists from China who generated the information (that team had published its findings based on the raw data in June 2020; ref. 10). Our colleagues in China contacted the authors of the June 2020 paper, retrieved the data and added them to the SARS-CoV-2 genome phylogenetic data published in our report. The data were from people who had an onset of illness in January, so they did not contribute any new information to the origins question.

In the report, and since, we have publicly called for any data supporting the lab-leak hypothesis to be published and submitted to the WHO. None has, so far.

Six priorities

To keep up the momentum for phase 2 studies, our team has met weekly since the publication of the joint report. We have continued collaboration with our Chinese co-authors, including work on a list of corrections to the phase 1 report. Both the international team and the Chinese team have now put forward to the WHO priorities for phase 2 studies, developed from the recommendations in the joint report.

The international team listed the following priorities:

Further trace-back studies. On the basis of disease reporting, look for early COVID-19 cases in all regions inside and outside China that have the earliest evidence for SARS-CoV-2 circulation.

Antibody surveys. Use standardized methods in the regions that have the earliest evidence for SARS-CoV-2 circulation (inside and outside China) to identify any places where infections occurred that were not observed through disease reporting.

Trace-back and community surveys. These will need to be conducted at sites of wildlife farms that supplied animals to markets in Wuhan in the months before human cases were recognized (inside and outside China, depending on supply-chain analysis).

Risk-targeted surveys of possible hosts. Assess wild bats and other potential reservoirs or intermediate hosts in China and neighbouring countries, and selected high-risk farmed animals (including those farmed for fur), for evidence of exposure.

Detailed risk-factor analysis. Analyse pockets of earlier cases evidenced from the antibody surveys or other studies, and conduct an assessment of all possible exposures.

Follow-up. Investigate any credible new leads.

Time's up

The search for the origins of SARS-CoV-2 is at a critical juncture. There is willingness to move forward from both the WHO international team and the Chinese team.

Crucially, the window is rapidly closing on the biological feasibility of conducting the critical trace-back of people and animals inside and outside China. SARS-CoV-2 antibodies wane, so collecting further samples and testing people who might have been exposed before December 2019 will yield diminishing returns. Chinese wildlife farms employ millions of people (14 million, according to a 2016 census[11]) and supplied live mammals to cities across China, including Wuhan[3]. In response to the SARS-CoV-2 pandemic, many of these farms are now closed and the animals have been culled, making any evidence of early coronavirus spillover increasingly difficult to find.

> "The search for the origins of SARS-CoV-2 is at a critical juncture."

In July, four months after the full report and five months after our debriefing, the WHO informed member states of plans to create a committee that will oversee future origins studies. We are pleased to see both this and its implication that outbreak investigations will be conducted routinely, rather than in an ad hoc manner that could be perceived as politically motivated or with potentially punitive goals.

However, applying this new process to the continuing SARS-CoV-2 origins mission runs the risk of adding several months of delay. Member-state representatives would need to negotiate detailed terms around the sensitive issue of investigating laboratory practices, then nominate and select team members, who would then have to develop a work plan.

Therefore, we call on the scientific community and country leaders to join forces to expedite the phase 2 studies detailed here, while there is still time.

The authors

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The authors declare competing interests, see go.nature.com/3d2rmx6.

From: Morens, David (NIH/NIAID) [E] [b6 b6]
Sent: 9/9/2021 9:26:10 PM
To: Peter Daszak ([b6]) [[b6]]; Keusch, Jerry [b6] ([b6])
Subject: FW: 2021 reference from my EndNote library
Attachments: 2021-Horrified Anti-Vaxxer Discovers Every Ame.pdf

You heard it first here!

David

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☎ [b6] (assistant: Whitney Robinson)
301 496 4409
[b6]

From: Ksiazek, Thomas G. [b6]
Sent: Thursday, September 9, 2021 5:19 PM

To: Ksiazek, Thomas (Galveston National Labortory-UT) [redacted] **b6**
Subject: 2021 reference from my EndNote library

Bob Tesh sent a link to this article over earlier. Some of you may have already received it, I apologize for any duplication.

Onion piece, good one, also see the last sentence about ivermectin…

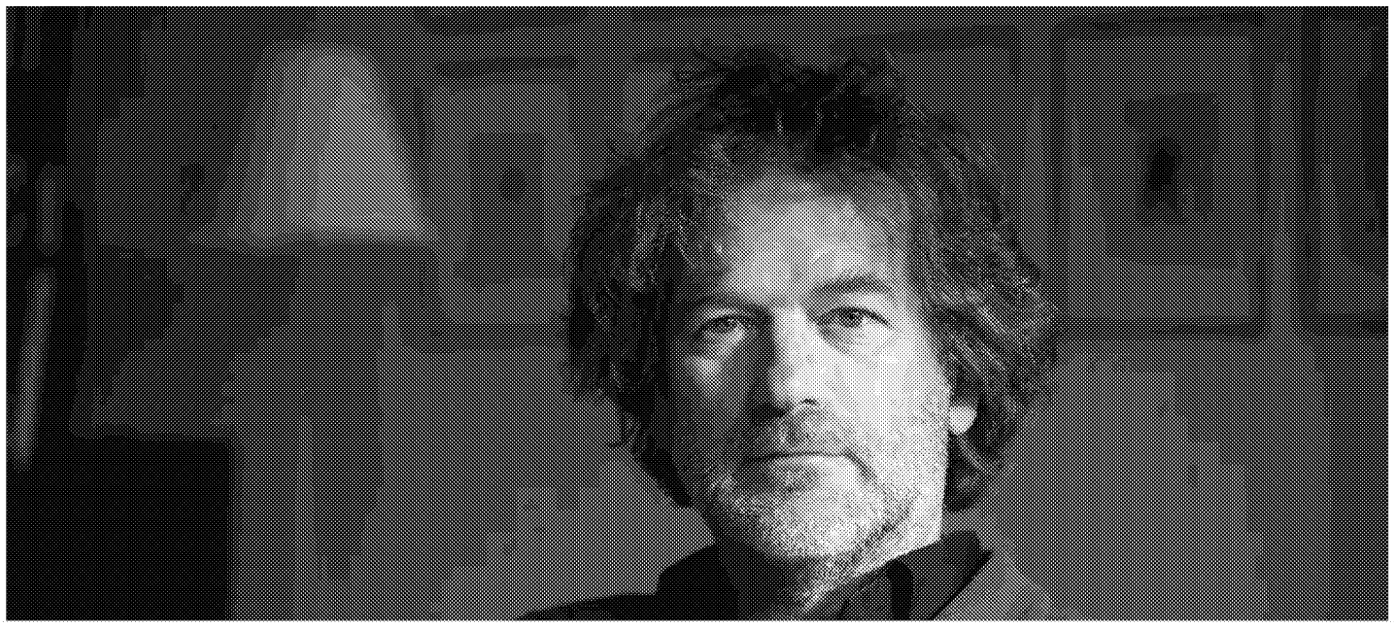
Tom Ksiazek

Anonymous. (2021, 20210909). **Horrified Anti-Vaxxer Discovers Every American Who Got Smallpox Vaccine In 19th Century Now Dead.** The Onion Retrieved 0909, 2021, https://www.theonion.com/horrified-anti-vaxxer-discovers-every-american-who-got-1847644353

NEWS IN BRIEF

Horrified Anti-Vaxxer Discovers Every American Who Got Smallpox Vaccine In 19th Century Now Dead

Today 12:55PM | Alerts



LYNCHBURG, VA—Astounded by the damning information, local anti-vaxxer Pete Dixon was reportedly horrified Thursday after discovering that every single American who got a smallpox vaccine in the 19th century was now deceased. "We're expected to follow along blindly with the CDC, but if people would simply look to the history, they'd see that the thousands of people who were inoculated against smallpox in the 1800s have since dropped dead," said Dixon, telling reporters that it was disgusting that the mainstream media had refused to share any stories about Americans who had taken the government-mandated vaccines, only to eventually perish from complications including respiratory failure, cancer, heart attack, stroke, or cholera. "They act like these shots are completely safe and tested, but I guarantee that future historians are going to look back on this time period centuries from now and discover that everyone who took the Covid vaccine is dead, too." Dixon added that despite the media's constant downplaying of alternative medicine, not a single person in the 19th century had died from ingesting ivermectin.

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From: Morens, David (NIH/NIAID) [E]
Sent: Mon, 1 Feb 2021 23:25:20 +0000
To: Aguilar, Patricia V.
Cc: (b)(6)
Subject: Re: ACAV webinar on COVID-19 variants

Peter, i meant to email earlier about this and the other matter we discussed. On the latter, i spoke with Tony and he would like for you to brief him on your return from Wuhan, when convenient for yiu

Hope all is well. Don't drink the Mao Tai!!!!!!!!
David
Sent from my iPhone
David M Morens
OD, NIAID, NIH

On Feb 1, 2021, at 17:51, Aguilar, Patricia V. (b)(6) wrote:

Dear Dr. Daszak:
On behalf of The American Committee on Arthropod-borne and zoonotic viruses (ACAV), we are honored to invite you to speak at the webinar on COVID-19 variants. The event will be scheduled for late February or early March.
We believe your voice would be a critical addition to our panel of renowned speakers. Please let me know whether or not you would be interested in participating as part of our panel. Thank you in advance for your consideration; we very much look forward to hearing from you.

Best Regards,

Patricia Aguilar, PhD
ACAV Chair 2021
Associate Professor, Department of Pathology
Associate Director, Center for Tropical Diseases
University of Texas Medical Branch
301 University Blvd
Galveston, Texas77550
(b)(6)
Ph: (b)(6)

From: Morens, David (NIH/NIAID) [E]
Sent: Sat, 11 Sep 2021 18:14:37 +0000
To: Peter Daszak
Cc: Gerald Keusch; Robert Kessler; Kristian Andersen; Eddie Holmes; Angie Rasmussen; Jason Gale
Bcc: Morens, David (NIH/NIAID) [E]
Subject: Re: origins of SARS-CoV-2

She seemed like a good and diligent reporter so i was kinda pissed that she misquoted me. But as i am sure you know, this is what happens when reporters scribble down notes without thinking, and then later patch it all together and edit it down. What i said to her in an hour of interview, including many addition things not in the article, was unmistakeably NOT what she wrote, at least not in that part. Grr…. d

Sent from my iPhone
David M Morens
OD, NIAID, NIH

On Sep 10, 2021, at 21:17, Peter Daszak (b)(6) wrote:

Yes – just saw that story – not much new in it and I did enjoy your quote even though I didn't know what you meant was a waste of time!! I think we all get it. In the end the give-away for this story is 1) the first pic they put up (the ubiquitous me in a car in front of the WIV with security guards) and 2) the quotes they highlight in giant font which are about the lab leak, nothing else… Tedious to be honest.

I've pasted it because it's subscription only and you shouldn't be giving them money…

Members of the World Health Organization team tasked with investigating the origins of COVID-19 arrive at Wuhan Institute of Virology earlier this year.
PHOTOGRAPH BY THOMAS PETER, REUTERS

- SCIENCE

- CORONAVIRUS COVERAGE

Why it's so tricky to trace the origin of COVID-19

A 90-day investigation into the source of SARS-CoV-2 has shown consensus that the virus was not engineered. But many other elements remain a mystery.

BY PRIYANKA RUNWAL
PUBLISHED SEPTEMBER 10, 2021
• 20 MIN READ

After 20 months, 219 million cases, and more than four million deaths, we've learned a lot about the COVID-19 pandemic. But the most polarizing question and central mystery remains: We still don't know where the virus that started it all actually came from. Most experts were not surprised in late August when a 90-day investigation by the U.S.

intelligence community came up empty-handed on the origin of the SARS-CoV-2 virus. A brief, one-page unclassified summary released on August 27 revealed the only point on which the intelligence community agreed: that the virus was "not developed as a biological weapon."

Understanding where, when, and how this pandemic started is important information for public health officials seeking to control its spread and even prevent future outbreaks. If the source of the virus is found to be bats or another animal, as many experts suspect, preventative measures might include curtailing contact between that animal and those living or working in close proximity. Measures could involve regular surveillance of animals and humans living where the virus is endemic to reduce the likelihood of future spillover—when a virus is transmitted to a human, directly or via a host animal, triggering an outbreak.

The results may also lead to broader policy decisions to curb deforestation and habitat fragmentation, and to block human settlements in known viral hot zones. Knowing where the pandemic virus arose could also lead to changes in human behavior, such as reducing demand for bushmeat and wildlife-derived products that drive the illegal wildlife trade. And if the virus is instead found to have leaked from a lab, that finding would no doubt spur scientists and policy-makers to find safer ways to study these pathogens.

> Historically looking back, we can have lab leaks.
>
> JESSE BLOOMVIROLOGIST

That's why scientists support a thorough, evidence-based investigation for the origins of COVID-19. But similar inquires during past epidemics have taken months to years to yield answers, and in several cases, the mystery remains unresolved.

"Science takes time," says Arinjay Banerjee, a virologist at the University of Saskatchewan in Canada. "To go back and confidently identify the source is a difficult task."

Earlier this year, an international World Health Organization team visited the city of Wuhan, China, to assess the evidence China had provided about the origin of SARS-CoV-2. In a report that summarized their findings, the WHO suggested that it was "likely to very likely" that the virus first spread from infected bats to humans via an intermediate host animal.

This was the case with the 2002 SARS-CoV outbreak—the first pandemic of the 21st century; the virus most likely spilled over from cave-dwelling horseshoe bats in China to palm civets sold in live animal markets, where it reached humans. Similarly, the 2012 MERS-CoV epidemic is suspected to have originated in bats and was later transmitted to dromedary camels, which infected humans.

That WHO report also deemed a laboratory leak from the Wuhan Institute of Virology, known for its work with coronaviruses, as "extremely unlikely." But the conclusion sparked backlash from scientists and governments around the world, who argued that it's still too early to rule out a lab leak based on the evidence in hand. Other experts caution that political motivations could drive people to hasty conclusions.

"There is a progenitor virus out there somewhere, and we should look for it," says David Morens, senior scientific adviser on epidemiology to Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases. "But at some point, it crosses over from doing due diligence to wasting time and being crazy. We may have seen that point already."

Here's what we know so far about the scientific investigation into the origin of the pandemic, and what still needs to be done to find clear answers.

What evidence do virus detectives seek?

Tracing the origin of a virus requires extensive fieldwork, thorough forensics, and a fair bit of luck. The laborious endeavor can take years until scientists have the evidence they need to point to a source.

For diseases originating from animals, that evidence is typically a genetic match between virus sequences obtained from an animal and those from some of the first confirmed patients. The match may not be 100 percent, because viruses gather mutations or new genes over time and as they jump hosts. But with enough investigation, scientists have found nearly perfect matches of around 99 percent or better for some viruses—including the ones responsible for two previous coronavirus outbreaks.

Cat-like tree-dwelling palm civets, considered a delicacy and sold in street markets, quickly became the focus during the 2002-04 outbreak of Severe Acute Respiratory Syndrome (SARS) that emerged in China's Guangdong Province, which resulted in more than 8,000 cases and nearly 800 deaths in 29 countries. Some of the first SARS cases included several infected restaurant chefs handling a variety of animals. Blood tests of animal traders in the region showed higher prevalence of antibodies against the SARS-associated coronavirus compared to healthy controls, with the highest levels recorded among those who traded primarily in masked palm civets.

A 2003 paper also showed that the nasal swab of a masked palm civet obtained from a live animal market in Guangdong yielded a 99.8 percent match between the full genome sequence of the SARS-CoV-like virus isolated from the civet and virus from a human. This indicated that the SARS-CoV-like virus had recently infected civets at the market.

But it became evident that these furry mammals weren't the original sources, as the virus was mostly absent among farmed masked palm civets prior to reaching the markets, and it was not widely circulating in its wild populations. Suspecting bats to be the natural reservoirs, given that they harbor other zoonotic viruses, researchers sampled blood, fecal, and throat swabs of bats in regions across China and in Hong Kong.

More than 10 years later, they identified horseshoe bats in a remote cave in southwestern China's Yunnan Province sporting virus strains that contain all the genetic pieces recorded in viral genomes from human patients. It's possible the strain that precipitated the 2002

epidemic was a product of recombination of different genetic strains found in these bats.

Scientists later used lessons from tracing the origins of the SARS virus to investigate the source of the 2012 Middle East Respiratory Syndrome (MERS) coronavirus outbreak, which infected more than 2,000 people in 37 countries and killed nearly 900.

The virus was first isolated from a 60-year-old businessman who died of severe pneumonia and multi-organ failure in June 2012 in a hospital in Jeddah, Saudi Arabia. Early efforts to trace the source focused on bats. In Saudi Arabia, throat swab, urine, fecal, and blood samples from wild bats, including those occurring in the area where the first patient lived and worked, showed indications of a MERS-like coronavirus in one Egyptian tomb bat fecal sample. But without a full genome sequence, the role of bats could not be evaluated.

Meanwhile, anecdotal reports suggested some patients had been exposed to dromedary camels or goats. A 2013 study found antibodies against MERS in blood samples collected from retired racing camels in Oman, which were missing in blood from European sheep, goats, and cattle. Similar blood surveys conducted in several countries within the Arabian Peninsula, Egypt, and Spain's Canary Islands also showed the presence of antibodies in camel blood, indicating the hoofed mammals were once infected by the virus.

But the strongest evidence of dromedary camels' involvement came from Qatar in October 2013, where a camel herd owner and his co-worker were diagnosed with MERS. Nasal swab tests indicated five of 14 camels on their farm were MERS-positive. Further, whole viral genome sequences obtained from humans and camels were 99.5 to 99.9 percent identical.

Scientists believe camels are the intermediate hosts and suspect bats to be the original reservoirs of MERS-CoV. That's because some bat species, like the vesper bats in South Africa, harbor viruses that are related to the one that causes MERS. But there's still an evolutionary gap between those bat viruses and the human or camel versions.

“We still haven’t found those viruses that are very, very close,” says virologist Chantal Reusken at the Dutch Institute for Public Health and the Environment in the Netherlands.

> This is all weaponized politically, which is unfortunate.
>
> DARRYL FALZARANOVIROLOGIST

What we know so far about COVID-19’s origin story

One key difference with the SARS and MERS outbreaks is that scientists were able to identify the intermediate animal sources within months of their onset. For COVID-19, that link remains unknown.

In December 2019, some of the early COVID-19 cases in Wuhan were reported among vendors linked to the Huanan market, which was selling wild and farmed animals including badgers, racoon dogs, civets, hare, rats, snakes, and crocodiles.

Between January 1, when the market was closed, and March 2020, officials with the Chinese Center for Disease Control and Prevention collected more than 900 swab samples of floors, walls, or surfaces of objects from the Huanan market, its drainage system, and the surrounding markets. They found that 73 samples were SARS-CoV-2 positive.

The Chinese CDC also collected more than 2,000 fecal and body swab samples from alive or frozen animals in Huanan and other markets in Wuhan, from animals raised by some Huanan market suppliers, and from several wild animals found in nearby provinces in southern China.

According to the WHO report, all those samples tested negative for SARS-CoV-2, and in some cases, for antibodies against the virus. But this sampling missed many live animals typically sold when the markets were open. Similar tests of thousands of livestock and poultry samples collected from across China in 2018, 2019, and 2020 as part of routine animal surveillance also tested negative for SARS-CoV-2.

Last year, scientists detected SARS-CoV-2-like virus strains in Sunda pangolin tissue samples that were seized in anti-smuggling operations in southern China in 2017 and 2018. Sought for their meat and scales

used in traditional Chinese medicine, these pangolins are among the world's most trafficked mammals. But with only an 85.5 to 92.4 percent match between the human SARS-CoV-2 genome sequence and those obtained from pangolins, scientists can't mark them as the relevant hosts. Also, a team surveying Wuhan's wet markets between May 2017 and November 2019 found no pangolins being sold there.

And as was the case with MERS, comparing genome sequences from early COVID-19 patients with SARS-like coronavirus sequences directly from bats hasn't yet yielded a close enough match, either.

So far, the closet relative is a coronavirus labelled RaTG13. It was discovered in Chinese horseshoe bats near a cave in Yunnan shortly after six miners fell sick and three of them died due to an unknown respiratory illness in 2012. RaTG13 shares 96.2 percent of its genome with human SARS-CoV-2. A coronavirus dubbed RmYN02 and derived from Malayan horseshoe bat poop collected in Yunnan Province in 2019 is 93.3 percent similar.

Scientists have also identified SARS-CoV-2-related viruses in bats outside China. This January a team isolated a coronavirus sequence showing a 92.6 percent match from two Shamel's horseshoe bats sampled in Cambodia in 2010. And in February a coronavirus named RacCS203 taken from acuminate horseshoe bats in Thailand's Chachoengsao Province showed 91.5 percent similarity in its genetic code.

Matches above 90 percent may sound high, but in genomic terms it's a wide evolutionary gap. After all, humans and bonobos are an 98.7 percent genetic match.

"The big problem is that bats are everywhere and there are so many species with a huge diversity of viruses, including coronaviruses," says Bart Haagmans, a virologist at the Erasmus Medical Center in the Netherlands. "It's difficult to find the bats with the virus that started the outbreak."

Why the lab-leak suspicion persists

Many scientists believe that SARS-CoV-2 originated in nature and is unlikely a product of laboratory engineering. In a March 2020 Nature Medicine study, for instance, Kristian Andersen, a virologist at the Scripps Research Institute in La Jolla, California, and his colleagues showed that some genetic features once considered unique to SARS-CoV-2—and thus potentially human-made—are found in nature. They found features like the furin cleavage site, which facilitates the virus's entry into human cells, and the receptor binding domain that allows the virus to anchor itself to human cells,also present in related viruses isolated from Malayan pangolins and bats.

But despite its likely natural origin, the theory that SARS-CoV-2 could have escaped from a laboratory continues to pique the interest of some scientists, several politicians, and many in the larger public sphere.

Part of the suspicion comes from the fact that the pandemic emerged very close to the Wuhan Institute of Virology, where researchers have been surveying bats for coronaviruses and maintaining a database of samples and virus sequences. "People look at the coincidence," Andersen says.

The institute's location doesn't surprise him, though. Wuhan is an extremely connected and populous city with several wet markets, and in the past, bat coronaviruses have been identified from the larger region. "There are labs close to where outbreaks can happen, and where these outbreaks happen is where you want to study them," Andersen says.

Still, experts and observers argue it's possible members of the Wuhan Institute of Virology staff were infected due to safety lapses while working with the SARS-CoV-2 virus or during fieldwork, and then they inadvertently spread the disease.

> What's frustrating is that with some transparency, it can all be cleared up.
>
> DARRYL FALZARANOVIROLOGIST

In a letter published in Science on May 14, some scientists suggested that the possibility of the virus escaping from the lab was not given due consideration during the WHO investigation. In a March 30 press

briefing, WHO program manager Peter Ben Embarek, who led the COVID-19 fact-finding mission to China said: “Since [the lab leak theory] was not the key or main focus of the joint studies, it did not receive the same depth of attention and work as the other hypotheses.”

The Wuhan institute’s leading bat virologist Shi Zhengli said her laboratory records didn’t indicate any match between virus samples her team had collected from China’s bat caves and SARS-CoV-2 sequences. However, the WHO-China team couldn’t access those records.

Laboratory accidents aren’t unheard of. In Singapore, Taiwan, and China, four researchers in labs studying the SARS virus were accidently infected in the aftermath of the initial outbreak. In 2014, dozens of workers at the U.S. Centers for Disease Control and Prevention in Atlanta were potentially exposed to live anthrax bacteria resulting from a breach in safety procedures.

“Historically looking back, we can have lab leaks,” says Jesse Bloom, a virologist at the Fred Hutchinson Cancer Research Center and lead author of the Science letter. “To be confident about what happened, we need more investigation.”

Fresh controversy erupted when a May 23 Wall Street Journal story reported that an undisclosed U.S. intelligence report claimed three researchers at the Wuhan institute sought hospital care in November 2019 for “symptoms consistent with both COVID-19 and common seasonal illness.” The identity of those researchers or the exact illness they had still remains unknown.

The WHO report found no records of COVID-19-related illness or evidence of infection among the institute’s staff prior to December 2019. However, the team didn’t have access to raw patient data from 174 early COVID-19 cases identified in Wuhan, half of which weren’t connected to the Huanan market. This information could aid the quest to trace the pandemic’s origin.

“What’s frustrating is that with some transparency, it can all be cleared up,” says virologist Darryl Falzarano at the University of Saskatchewan. “This is all weaponized politically, which is unfortunate.”

What happens next

Several molecular dating analyses have suggested that SARS-CoV-2 was potentially circulating as early as October 2019. The WHO report therefore recommends searching for SARS-CoV-2 antibodies in stored blood bank samples. This could help resolve the timeline for when the virus emerged, but the search for what started the pandemic may be a long and arduous one.

“You may have to spend the next 10 years sampling animals to find something that’s really close,” Falzarano says. “But you may not even find that perfect linkage.”

The WHO team recommends searching for SARS-CoV-2-related viral sequences and antibodies in horseshoe bats mainly in southern China and in East and Southeast Asia. Similar surveys for potential intermediate host species could include pangolins, minks, rabbits, raccoon dogs, and domesticated cats, all of which have been infected by SARS-CoV-2 in the recent past.

Other projects include tracing wildlife farms that supplied markets in Wuhan and testing susceptible animals and people interacting with them, and analyzing the role of cold chains and frozen foods as a transmission source.

Recently, unpublished grant proposals and annual reports obtained by The Intercept gave insight into National Institutes of Health-funded coronavirus research in Wuhan in collaboration with New York-based non-profit EcoHealth Alliance.

In sophisticated, high-security facilities called Biosafety Level 3 labs, scientists tested the ability of new bat coronaviruses to infect humanized mice cells. These tests often used hybrid viruses created using a previously known SARS-like strain as the backbone and adding

what's called a spike protein from a new virus that facilitates its entry into cells.

"It's standard virology research and it's addressing a really key question: What are the potential viruses that could emerge [as a potential threat to humans] and where are they found," says Andersen, who reviewed the documents on National Geographic's request. To him, the information doesn't indicate that SARS-CoV-2 was engineered in the Wuhan laboratory as the backbone strain used in their experiments is not the backbone of SARS-CoV-2.

Still, even before the grant documents came to light, some pundits were wondering if the laboratory will be investigated further for conducting any risky experiments or biosafety breaches.

"We don't know exactly what happened," Bloom says. "So, we can't rule out all possibilities"

Editor's Note: This story originally misspelled the name of the virologist at the Scripps Research Institute in La Jolla. It is Kristian Andersen.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
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From: Morens, David (NIH/NIAID) [E](b)(6)
Sent: Friday, September 10, 2021 4:33 PM
To: Peter Daszak(b)(6) ; Gerald Keusch (b)(6) ; Robert Kessler (b)(6) Kristian Andersen (b)(6) ; Eddie Holmes >; Angie Rasmussen (b)(6) Jason Gale <j.gale@bloomberg.net>
Subject: Fwd: origins of SARS-CoV-2

This lady totally misquotes me because she did't read her own notes and didn't let me go over the text as agreed to. The « waste of time » comment was about chasing lab leaks, not searching for viral origins

Grrrrrr……. d

Sent from my iPhone
David M Morens
OD, NIAID, NIH

Begin forwarded message:

From: Priyanka Runwal (b)(6)
Date: September 10, 2021 at 16:24:14 EDT
To: "Morens, David (NIH/NIAID) [E]" (b)(6)
Subject: Re: origins of SARS-CoV-2

Hi David,
The story was finally published today: https://www.nationalgeographic.com/science/article/why-its-so-tricky-to-trace-the-origin-of-covid-19
I really appreciate you taking the time to speak with me and sharing your insights.

On Tue, Sep 7, 2021 at 12:52 PM Priyanka Runwal (b)(6) wrote:
(b)(6) .

On Tue, Sep 7, 2021 at 12:51 PM Priyanka Runwal (b)(6) wrote:
Sounds good. Thank you.
I'm at (b)(6) . Call me anytime.

On Tue, Sep 7, 2021 at 12:45 PM Morens, David (NIH/NIAID) [E] (b)(6) wrote:
No, but give me a number to call you. In a meeting now but should be free within the hour

David

David M. Morens, M.D.
CAPT, United States Public Health Service
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301 496 4409
(b)(6)

From: Priyanka Runwal (b)(6)
Sent: Tuesday, September 7, 2021 12:37 PM
To: Morens, David (NIH/NIAID) [E] (b)(6)
Subject: Re: origins of SARS-CoV-2

Thank you for your reply. I can call you now or any other convenient time you prefer.
Is this the best number to reach you: (b)(6) ?

On Tue, Sep 7, 2021 at 12:26 PM Morens, David (NIH/NIAID) [E] (b)(6) wrote:
Sure, let me know…..

David

David M. Morens, M.D.
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(b)(6)

From: Priyanka Runwal (b)(6)
Sent: Tuesday, September 7, 2021 12:26 PM
To: Morens, David (NIH/NIAID) [E] (b)(6)
Subject: Re: origins of SARS-CoV-2

Dear David,
We spoke a while ago and my editor is looking to publish the story tomorrow.
I have, of course, included quotes from our earlier interview, but would you have any comment on the FOIA-ed grant proposals and suggestions of gain-of-function research The Intercept story cites:https://theintercept.com/2021/09/06/new-details-emerge-about-coronavirus-research-at-chinese-lab/
Your input would be helpful to our readers. I wouldn't take more than 10 minutes of your time. Let me know. Thank you.

On Fri, Jul 30, 2021 at 5:46 PM Priyanka Runwal (b)(6) wrote:
Thank you so much, David.

On Fri, Jul 30, 2021 at 3:50 PM Morens, David (NIH/NIAID) [E] (b)(6) wrote:
Hi Priyanka, attached is the article I mentioned that came out yesterday, expaining in part why legitimate scientists are afraid to speak out about the "origins" stories.

David

David M. Morens, M.D.
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From: Priyanka Runwal (b)(6)
Sent: Thursday, July 29, 2021 6:36 PM
To: Morens, David (NIH/NIAID) [E] (b)(6)
Subject: Re: origins of SARS-CoV-2

Hi David,
Here are my questions:
1) Given past pandemics, what about the SARS-CoV-2 origin narrative/debate surprises you?
2) As an expert, what's the proof you're looking for to pin down the origin--either in nature or the much-debated lab leak/engineering?
Essentially, what evidence will convince you of the rightful SARS-CoV-2 origin.
3) In the same context, what are key data/pieces of evidence we should have had by now but are missing? This could touch on the early surveillance China did and the WHO team reviewed.
4) Are there any questions about the origin that we (media) aren't asking or science we aren't understanding/appreciating that we should?

Please let me know when and what number to call you tomorrow. Thanks

On Thu, Jul 29, 2021 at 10:47 AM Morens, David (NIH/NIAID) [E] (b)(6) wrote:
Great, TY,

David

David M. Morens, M.D.
CAPT, United States Public Health Service
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(b)(6)

From: Priyanka Runwal (b)(6)
Sent: Thursday, July 29, 2021 10:15 AM
To: Morens, David (NIH/NIAID) [E] (b)(6)
Subject: Re: origins of SARS-CoV-2

Later tomorrow works for me.
I really appreciate you making the time.
I'll send some questions your way this afternoon. Thanks again.

On Thu, Jul 29, 2021 at 10:03 AM Morens, David (NIH/NIAID) [E] (b)(6) wrote:

Possibly later tomorrow… My schedule is a bit messed up until next Tuesday as I am both working and have guests in town. My best times are typically late afternoons, like 4 or 5ish…. Also, it would be helpful if you could send me a few more sentences about specifically what you are looking for, so that I can perhaps pull out some of the key manuscripts, Ty,

David

David M. Morens, M.D.
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From: Priyanka Runwal (b)(6)
Sent: Thursday, July 29, 2021 10:05 AM
To: Morens, David (NIH/NIAID) [E] (b)(6)
Subject: Re: origins of SARS-CoV-2

Hi David,
Thank you so much for your email.
I'm happy to work around your schedule to make this interview possible.
Would anytime this week work for you?

On Thu, Jul 29, 2021 at 9:56 AM Morens, David (NIH/NIAID) [E] (b)(6) wrote:

Hi Priyanka, our media office here suggested you may want to speak to me about the origins of SARS-CoV-2. Happy to do that, schedules permitting.

David

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Best,

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@priyanka_runwal
Science, environment & health journalist
Bylines: The New York Times, Scientific American, STAT, National Geographic, Audubon Magazine, Science News, Live Science, others

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Bylines: The New York Times, Scientific American, STAT, National Geographic, Audubon Magazine, Science News, Live Science, others

From: Peter Daszak
Sent: Wed, 28 Jul 2021 10:36:06 -0400
To: Morens, David (NIH/NIAID) [E]
Cc: Keusch, Jerry; Robert Kessler; Sturchio, Jeff
Subject: RE: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

That said – the Intercept story provides the fullest explanation yet of why this is not considered Gain of function (P3CO) relevant by NIH:

Fauci did not get a chance to explain during the hearing what the scientific basis was for the determination by NIAID biologists that the experiments conducted at the Wuhan Institute of Virology, described in a paper published in 2017, were not subject to a temporary pause on the funding of gain-of-function research imposed during the Obama administration in 2014, which was lifted in 2017 after Trump became president.

But in a statement provided to The Intercept on Monday, NIAID explained the reasoning behind its review of the experiments conducted at the Wuhan Institute on behalf of EcoHealth Alliance, a nonprofit in New York that works with researchers in China to study viruses that have the potential to jump from bats to humans. The agency wrote that its scientists had concluded the pre-2017 experiments in Wuhan were not barred by the temporary pause on gain-of-function research, "because they were not reasonably expected to increase transmissibility or virulence of these viruses in humans."

"Under the grant, EcoHealth Alliance proposed research to create chimeric viruses by placing a small portion of newly identified, evolutionarily distant, bat coronaviruses into another well characterized bat coronavirus that has never been demonstrated to infect humans called WIV1," NIAID wrote. "The purpose of this work was to examine whether the newly discovered viruses were able to use the human ACE2 receptor like WIV1 and other SARS-related coronaviruses already do. In the context of these experiments, this well-characterized bat coronavirus would be considered the parental strain against which the function of the new chimeric viruses would be assessed. With this comparison, the newly created chimeric viruses did not gain any function relative to the parental strain; the chimeric viruses did not replicate in cell culture any better than the parental WIV1. In addition, research that had been published in peer-reviewed scientific journals demonstrated that viruses similar to those proposed under the grant had reduced pathogenicity as compared to the parental viruses. For these reasons, it was not reasonably anticipated that the viruses involved in research under the grant would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route, and therefore did not meet the criteria for gain-of-function research described in the research funding pause."

Cheers,

Peter

Peter Daszak
President

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Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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From: Morens, David (NIH/NIAID) [E] (b)(6)
Sent: Wednesday, July 28, 2021 10:29 AM
To: Peter Daszak (b)(6)
Cc: Keusch, Jerry ((b)(6)) (b)(6); Sturchio, Jeff ((b)(6)) (b)(6)
Subject: RE: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

I wouldn't trust them either, given their history which I didn't know. I'll try to remember to copy Robert K, and ping me if I forget.

Many of these things come from our OD news sweeps, which go on 24-7. But they don't get anywhere near everything, as they are more interested in Ton's press coverage than science itself.

David

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From: Peter Daszak (b)(6)
Sent: Wednesday, July 28, 2021 10:10 AM
To: Morens, David (NIH/NIAID) [E] (b)(6) Keusch, Jerry (b)(6)
Cc: Robert Kessler (b)(6) Jeff Sturchio (b)(6)
Subject: RE: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

Thanks for sharing David. Please cc Robert Kessler in on these in case he also misses them. I'm also cc'ing Jeff Sturchio who's working with us to navigate the media attacks at the moment.

This reporter contacted me, and I refused to talk, even though I suspected he would do a decent job. I think I'm the person he says 'supports this sort of research but has been worn down by death threats'.

I actually like the tenor of the story – it's factually correct and points out the danger of people like Lipsitch and Ebright using a false premise to support their efforts to re-litigate 'gain of function'. It's

good to see Lipsitch having to be factually correct here and agree that Rand Paul massively overstated their case!

One of the reasons I didn't speak with this reporter, by the way is that the journal (The Intercept) is one of the orgs that's FoIA'd 38 of EcoHealth's NIH grants and annual reports going back to 2001– just wasn't sure I could trust their motives!

Cheers,

Peter

Peter Daszak
President

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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From: Morens, David (NIH/NIAID) [E] (b)(6)
Sent: Wednesday, July 28, 2021 9:55 AM
To: Peter Daszak ((b)(6)) (b)(6); Keusch, Jerry ((b)(6)) (b)(6)
Subject: FW: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

David

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From: Folkers, Greg (NIH/NIAID) [E] (b)(6)
Sent: Tuesday, July 27, 2021 2:48 PM
Subject: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

At a Senate hearing on July 20, 2021, Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, told Sen. Rand Paul that he resented the suggestion that he had lied to Congress. Photo: J. Scott Applewhite/Pool/AFP via Getty Images

Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research

By politicizing the debate over virus-modifying research, the senator has thrilled conservatives but discouraged scientists from weighing in.

Robert Mackey

July 27 2021, 10:14 a.m.

A decadelong debate over pandemic preparedness that has divided some of the world's leading biologists into opposing camps, for and against so-called gain-of-function research — in which deadly pathogens that could cause pandemics are artificially enhanced for study in the lab — has all but ground to a halt in the past week, thanks to Sen. Rand Paul.

That's because the Republican senator from Kentucky politicized the argument last week, by cherry-picking expert opinions from critics of the research who call it too risky to pursue, to publicly accuse Dr. Anthony Fauci of lying to Congress, when he said that his National Institute of Allergy and Infectious Diseases had never funded gain-of-function studies at the Wuhan Institute of Virology in China.

Paul's made-for-television broadside against Fauci thrilled Fox News hosts and colleagues like Rep. Jim Jordan, the Ohio Republican who has also pushed the debunked conspiracy theory that research financed by Fauci's agency, which some experts describe as gain-of-function, could have led to the development of SARS-CoV-2, the deadly coronavirus that causes the disease Covid-19, in the Wuhan lab.

Fauci rejected Paul's claim that research carried out in Wuhan before 2017 with some support from the NIAID met the definition of gain-of-function and pointedly explained that it was impossible to make SARS-CoV-2 from the coronavirus used in that study.

Almost as soon as the heated exchange concluded, the senator's staff uploaded a truncated version of the video on his YouTube channel under the headline, "Dr. Fauci Caught Lying about NIH Funding in Wuhan."

That video was edited by Paul's staff so that it ends before Fauci responded to the senator's harangue by saying, "I totally resent the lie that you are now propagating, senator, because if you look at the viruses that were used in the experiments … it is molecularly impossible … to result in SARS-CoV-2."

On social networks, Republican operatives unconcerned with the facts — like Richard Grenell, the Twitter troll who served as Donald Trump's director of national intelligence for three months — cheered on Paul's attack.

But Paul's false claim that Fauci's supposed support for gain-of-function studies gave him "responsibility for 4 million people dying around the world from a pandemic," and the ensuing frenzy in the conservative media, also caused some previously outspoken biologists who have made the case against such experiments to fall silent.

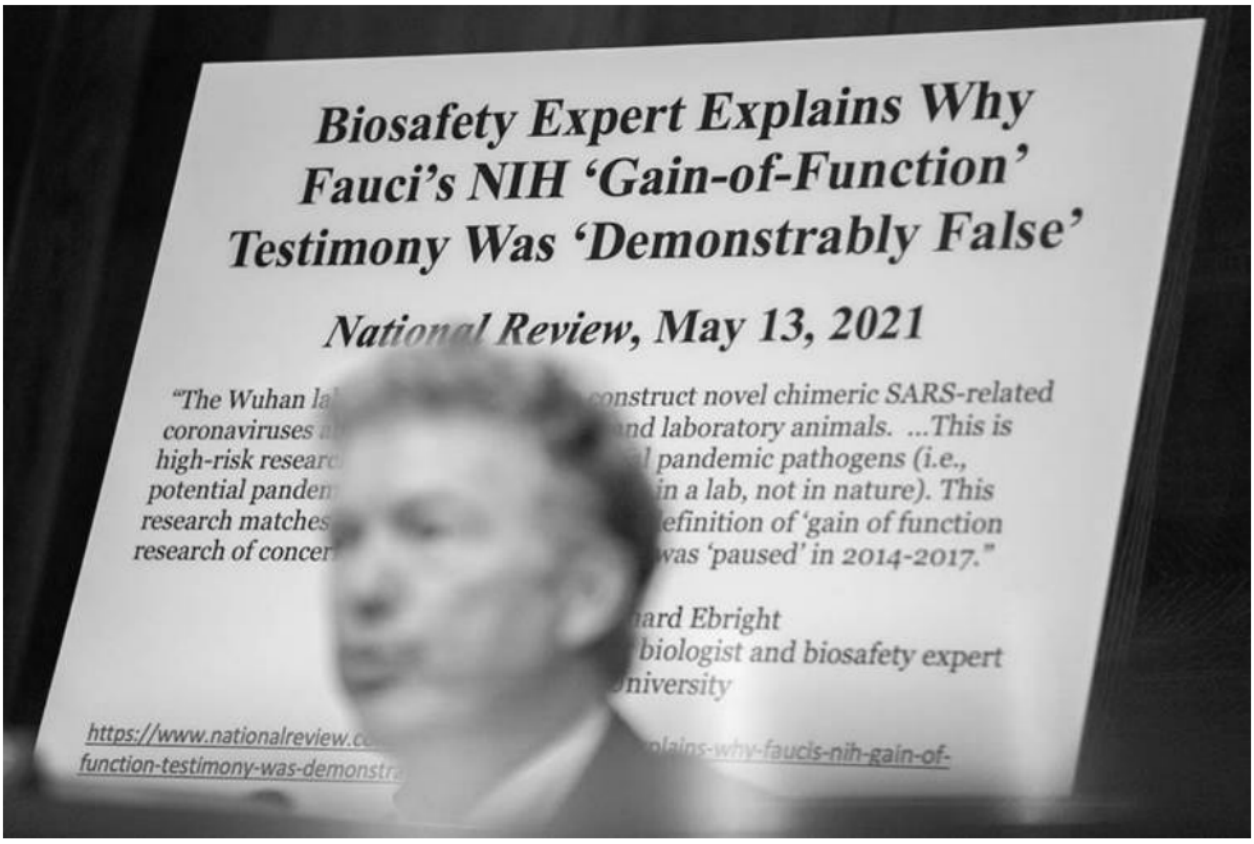
In the wake of Paul's attack on Fauci, several prominent scientists who question the wisdom and safety of gain-of-function experiments — in which biologists deliberately create pandemic-causing pathogens in the lab in order to better prepare to combat them should they evolve in nature — refused to speak to me on the record. One after another, they said Paul's patently false claim that Fauci was to blame for the pandemic, and his selective outrage at gain-of-function research only when conducted in China, made it all but impossible for them to say anything about the pre-pandemic experiments in Wuhan without being vilified by partisans.

One biologist who supports such research told me that he would have liked the opportunity to correct what he called misinformation about the experiments, but had been worn down by death threats.

To recap, at a hearing in May, Paul first accused Fauci of having supported gain-of-function research in Wuhan, which the senator, who is also a doctor, misleadingly defined as "experimenting to enhance the coronavirus's ability to infect humans." In fact, the coronavirus that researchers experimented on between 2014 and 2017 at the Wuhan Institute, with some financial support from the NIAID, was from a strain found in bats that is not closely enough related to SARS-CoV-2 to have been used to fabricate the virus that causes Covid-19 in a lab.

Fauci also insisted that his agency, which is part of the National Institutes of Health, had never funded gain-of-function research in Wuhan.

When Fauci returned to the senate committee last week, Paul confronted him with the words of Richard Ebright, a molecular biologist at Rutgers University and a longtime critic of gain-of-function studies, who told the conservative magazine National Review that Fauci's testimony in May was "demonstrably false," since, in Ebright's opinion, the experiments at the Wuhan Institute, indirectly funded by the NIAID as part of a project to head off a pandemic, were "unequivocally" gain-of-function in nature.



Sen. Rand Paul, a Kentucky Republican, used a visual aid to accuse Dr. Anthony Fauci of lying to Congress during a Senate Health, Education, Labor, and Pensions Committee hearing on July 20, 2021.
Photo: Stefani Reynolds-Pool/Getty Images

Fauci insisted that the biologist Paul cited was simply wrong, saying experts at the National Institutes of Health had evaluated the Wuhan project and concluded that the experiments there did not meet the criteria for gain-of-function research used by the United States government.

The exchange between Paul and Fauci got even more heated when the senator seemed to imply that this research funded by Fauci's agency could have led to the development of SARS-CoV-2, the deadly coronavirus that causes Covid-19, in the Wuhan lab.

As Fauci correctly noted, that speculation was wildly misleading, since it was "molecularly impossible" for the type of coronavirus used in the pre-2017 experiments to have been manipulated in the lab to create SARS-CoV-2.

On that point, even some of the most outspoken critics of gain-of-function research on potential pandemic pathogens agree with Fauci. Kevin Esvelt, an MIT biologist who told PolitiFact in May that the experiments conducted in the Wuhan study should be considered gain-of-function also emphasized that those experiments "definitely did NOT lead to the creation of SARS-CoV-2."

(Esvelt, who worries that viruses developed through gain-of-function experiments in a lab could one day be used as weapons, told "The Open Mind" on PBS in March that whether the virus that caused the Covid-19 pandemic came from an animal or came from a lab, "it was not designed to be a weapon — because anyone good enough to make this thing could make a more devastating weapon.")

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Paul was also rebuked in May by Marc Lipsitch, a microbiologist and professor of epidemiology at Harvard University who brought together hundreds of scientists and experts in law and ethics in 2014 to call for amoratorium on gain-of-function experiments that could create highly transmissible, novel strains of dangerous viruses in laboratories.

Lipsitch wrote in a Twitter thread that in his attack on Fauci in May, Paul had "FALSELY" claimed that the working group Lipsitch assembled had "characterized work at the Wuhan Institute of Virology as gain-of-function." While he and many members of the working group "support proper investigation of SARS-CoV-2 origins including the lab leak hypothesis and continue to oppose many forms of GOF research," he added, "it is just fabrication to say we have made any statement as a group about work in Wuhan."

Fauci did not get a chance to explain during the hearing what the scientific basis was for the determination by NIAID biologists that the experiments conducted at the Wuhan Institute of Virology, described in a paper published in 2017, were not subject to a temporary pause on the funding of gain-of-function research imposed during the Obama administration in 2014, which was lifted in 2017 after Trump became president.

But in a statement provided to The Intercept on Monday, NIAID explained the reasoning behind its review of the experiments conducted at the Wuhan Institute on behalf of EcoHealth Alliance, a nonprofit in New York that works with researchers in China to study viruses that have the potential to jump from bats to humans. The agency wrote that its scientists had concluded the pre-2017 experiments in Wuhan were not barred by the temporary pause on gain-of-function research, "because they were not reasonably expected to increase transmissibility or virulence of these viruses in humans."

"Under the grant, EcoHealth Alliance proposed research to create chimeric viruses by placing a small portion of newly identified, evolutionarily distant, bat coronaviruses into another well characterized bat coronavirus that has never been demonstrated to infect humans called WIV1," NIAID wrote. "The purpose of this work was to examine whether the newly discovered viruses were able to use the human ACE2 receptor like WIV1 and other SARS-related coronaviruses already do. In the context of these experiments, this well-characterized bat coronavirus would be considered the parental strain against which the function of the new chimeric viruses would be assessed. With this comparison, the newly created chimeric viruses did not gain any function relative to the parental strain; the chimeric viruses did not replicate in cell culture any better than the parental WIV1. In addition, research that had been published in peer-reviewed scientific journals demonstrated that viruses similar to those proposed under the grant had reduced pathogenicity as compared to the parental viruses. For these reasons, it was not reasonably anticipated that the viruses involved in research under the grant would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route, and therefore did not meet the criteria for gain-of-function research described in the research funding pause."

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From: Peter Daszak
Sent: Thu, 19 Aug 2021 10:37:31 -0400
To: Morens, David (NIH/NIAID) [E]; Robert Kessler; Keusch, Jerry
Subject: RE: Wpost: How Chinese pressure on coronavirus origins probe shocked the WHO - and led its director to push back

Texting with the WHO mission team this morning, I mentioned how this mysterious "WHO spokesperson" keeps slagging off the team's work and making stories out of it that suit the DG's politics as he lines up for re-election. I suggested it's probably Gabby Stern, the WHO head of comms, who basically works for Tedros. (b)(6) confirmed that. It's a very successful political/communications strategy from the WHO DG that began as soon as Biden entered the WH. He undermined the report re. the lab leak publicly right after the Press conference from Wuhan. Despite this article he knew exactly what was in the report and no one "fell off their chair". The DG then publicly criticized it re. the lab leak, got praises from the US State Dept because it helped with their goals of looking tough on China, and then launched his campaign for a second term, no doubt with US backing as opposed to his first campaign. Slick politician, awful public health guy.

By the way, at one point after we returned from Wuhan, the DG openly tried to get us to change the conclusions of our poll that we held in China re. the lab leak, so it would be more likely than "extremely unlikely". Utterly shameless, and of course we refused to do that and pointed out we were reporting results of an actual poll that had already been openly reported on. This led to us (in particular myself and (b)(6)) arguing openly with the DG in a very ugly 2 hour zoom call.

Misinformation right from the top at WHO. Most of the senior staff around the DG are ashamed of his political maneuverings – (b)(6) and others were very quiet on the zoom call when the DG announced to the team that he'd be setting up a new structure and we'd have to re-apply for membership for Phase 2 through our governments this time.

Cheers,

Peter

Peter Daszak
President

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USA

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Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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From: Morens, David (NIH/NIAID) [E] (b)(6)
Sent: Thursday, August 19, 2021 9:52 AM
To: Peter Daszak ((b)(6)) (b)(6); Kessler, Robert ((b)(6)) (b)(6); Keusch, Jerry ((b)(6)) (b)(6)
Subject: FW: Wpost: How Chinese pressure on coronavirus origins probe shocked the WHO — and led its director to push back

David

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From: Folkers, Greg (NIH/NIAID) [E] (b)(6)
Sent: Thursday, August 19, 2021 8:41 AM
Subject: Wpost: How Chinese pressure on coronavirus origins probe shocked the WHO — and led its director to push back

How Chinese pressure on coronavirus origins probe shocked the WHO — and led its director to push back

By
Adam Taylor
Reporter
Today at 12:01 a.m. EDT

You're reading an excerpt from the Today's WorldView newsletter. Sign up to get the rest free, including news from around the globe, interesting ideas and opinions to know, sent to your inbox every weekday.

From the start of the coronavirus pandemic, the World Health Organization has been accused of being too soft on China. President Donald Trump last year accused the organizationof pushing "China's misinformation about the virus" as he threatened to withdraw U.S. funding. At one point, Japan's deputy prime minister labeled it the "China Health Organization."

But a new book that details the relationship between the United States, China and the WHO during the pandemic offers a more nuanced and revealing story. It shows how WHO Director General Tedros Adhanom Ghebreyesus cautiously praised China in public while pressuring it in private. And it shows how the Trump administration undermined this tactic with open hostility toward China and the WHO.

"Aftershocks: Pandemic Politics and the End of the Old International Order," written by Thomas Wright and Colin Kahl and due to be published Tuesday, reveals how Tedros lost patience with China: When a WHO scientist on a coronavirus origins probe announced in February that the idea that the virus leaked from a lab was "extremely unlikely" and unworthy of further investigation, senior WHO staff in Geneva were shocked. "We fell off our chairs," one member told the authors.

The team in Wuhan appeared to have given in to Chinese pressure to dismiss the idea without a real investigation. Later, when the WHO-China team released a report that again dismissed that scenario, Tedros pushed back, saying that the research was not "extensive enough" and that there had not been "timely and comprehensive data-sharing."

Since then, relations between the WHO and China have nosedived. Chinese officials said in July that they would not accept any further investigation into the origin of the coronavirus in China and accused the United States of pressuring scientists. The WHO last week released a statement that resisted the idea that "the origins study has been politicized, or that WHO has acted due to political pressure."

Wright is a scholar at the Brookings Institution who focuses on America's global relationships, and Kahl was recently confirmed as undersecretary of defense for policy in the Biden administration. In an interview, Wright said researching for the book revealed how the WHO's cautious approach toward China was at odds with the Trump administration's brash style, though both were driven by legitimate concerns about China under President Xi Jinping.

The World Health Assembly, a representative body of WHO member states, approved an investigation into the pandemic's origins in May 2020. Soon an international team of experts led by WHO official Peter Ben Embarek was convened to travel to Wuhan, the virus's epicenter, to work with Chinese colleagues.

As the pandemic worsened, it became clear this path would be difficult. Trump had initially praised Xi's handling of the outbreak in Wuhan. But as the virus surged in the United States in spring 2020, Trump recognized the political peril it presented him and turned on China.

The virus's origins in Wuhan were particularly disputed. Though some scientists said the virus probably spread from bats to humans via an unknown third animal — zoonotic spread — influential members of the Trump administration pushed the idea that the virus could have inadvertently leaked from a laboratory in Wuhan, implying China was at fault.

WHO member states had authorized a probe that was specifically focused on zoonotic spread, but even this was difficult. The arrival of the team was delayed. After four weeks in Wuhan, including two in quarantine, Ben Embarek said in a Feb. 9 news conference that the group had ruled that indirect zoonotic spread was "likely" and a lab leak was "extremely unlikely" and not worthy of further investigation.

Wright and Kahl report that WHO leadership in Geneva were "stunned" by their colleague's statement. They did not believe the team that went to Wuhan had the access or data to rule out the lab-leak theory. Tedros told the investigative team this, the book reports, but the team was "defensive," describing pressure from Chinese officials that led to a compromise.

In a documentary released last week, Ben Embarek described how Chinese officials had wanted no mention of a lab leak at all. The scenario was only included "on the condition we didn't recommend any specific studies to further that hypothesis," he said.

Despite Tedros's criticism, when the probe's findings were released in a report in March, it repeated that the lab scenario was "extremely unlikely." Afterward, according to the book, the WHO director general told China's envoy in Geneva that he would tell the truth about the report "even if China did not like it."

Accounts of Tedros's belated shift on China may be unlikely to win over his critics. One senior Trump official told Wright and Kahl that the WHO only got tough on China after Trump left office because the impulsive Republican had provided Tedros the "cover" of a "pantomime villain."

But there's little evidence a U.S.-backed tough approach would have worked either. According to Wright, then-Secretary of State Mike Pompeo, a lab-leak theory proponent, "undermined it by taking it too far," diminishing support from allies. Though some Trump officials recognized the pandemic's gravity early on, they viewed it through the prism of a "China problem," rather than a public health emergency, Wright said.

"That U.S.-China rivalry really shaped everything else," he added.
As an international organization with limited powers, the WHO is beholden to its member states. "The U.S. has to engage with the WHO, work with China at the WHO, push for WHO reforms, but ultimately it has to recognize that these reforms are very unlikely to take root because China and maybe others as well won't commit to higher levels of transparency," Wright said.
A Trump-era plan for an alternative — dubbed "America's Response to Outbreaks" — faltered because of bureaucratic issues and the president's own uninterest. Wright and Kahl call for an alternative called the Global Alliance for Pandemic Preparedness, wherein like-minded nations could supplement the WHO's work.
As for the WHO-backed probe into the coronavirus's origins? Beijing told foreign diplomats last week that the March report calling a lab leak unlikely must be "respected," while U.S. intelligence is nearing the end of a 90-day deadline set by President Biden to reveal more about the virus's origin.
At a media briefing on Wednesday, WHO emergencies chief Mike Ryan said the organization was working behind the scenes to increase confidence in an investigation, and "we are making headway on that, but I have to admit, that has not been easy."

From: Morens, David (NIH/NIAID) [E]
Sent: Fri, 20 Aug 2021 14:48:25 +0000
To: Wang Linfa; Jason Gale; (b)(6); (b)(6); Garry, Robert F; (b)(6)
Cc: Taubenberger, Jeffery (NIH/NIAID) [E] ((b)(6)); Memoli, Matthew (NIH/NIAID) [E] ((b)(6)); Manning, Jessica (NIH/NIAID) [E] ((b)(6))
Subject: RE: (BN) SARS Survivors Offer Clues on Protecting Against Future Scourges

Dear Linfa, thanks and again, this is a potentially very important test for epidemiologic study, as well as, obviously, pointing a very promising way forward in vacine development.

I have taken the liberty of copying some of my NIH colleagues on this email, and sent several of them your NEJM paper yesterday, although I forgot to attach the supplementary data.

My NIH colleagues Jeff Taubenberger and Matt Memoli, and others, have been working on both influenza and SARS-CoV-2 vaccines designed to induce broad cross-protective immunity, including human challenges with flu but, at this point, only animal studies with SARS-CoV-2.

Our NIH colleague Jessica Manning has a field site in Cambodia and as I believe I mentioned to you last month, has identified a set of banked serums from folks in rural Cambodia that light up with SARS-CoV-2 in binding assays but not in Nt.

A multiplex assay would be a boon to field epidemiology by potentially specifying the viruses that positive individuals had been exposed to, in association with studying bats in those areas as well.

I think Peter D has mentioned that he has a paper coming out very soon that estimates a very large number of residents in the geographic area of interest, basically S and SW China plus the SEA countries… In other words, the ecosystem within which these viruses circulate and spill over to humaans/other mammals seems to be very broad and large.

Very exciting, and I hope your work will lead not only to better vaccines but also epidemiologic study relating to “origin” as well as characterizing the nature and extent of human exposures to sarbecoviruses.

David

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From: Wang Linfa (b)(6)
Sent: Thursday, August 19, 2021 10:55 AM
To: Morens, David (NIH/NIAID) [E] (b)(6); Jason Gale <j.gale@bloomberg.net>; (b)(6);

(b)(6) ; Garry, Robert F (b)(6)
Subject: RE: (BN) SARS Survivors Offer Clues on Protecting Against Future Scourges

Thanks David.

We were able to make this discovery for a few reasons:

1. We had SARS survivors in Singapore who are willing to help
2. I was puzzled by the lack for cross-NAb in SARS patient sera against COVID, so wanted to know whether boosting with CVOID vaccine can make such antibodies more dominant
3. Last, but not the least, I had the multiplex sVNT which allowed accurate and reliable comparison of NAbs against different sarbecoviruses in a "drop of blood" literally. We did 10-plex, but we can go to all-sarbecovirus-in-one if we want

This same test platform will play a key role in our common interest: finding the origin and/or spillover events of sarbecoviruses, not just SARS-CoV-2.

So let me know if you have "high value" human or animal sera for testing.

Cheers,

LF

Linfa (Lin-Fa) WANG, PhD FTSE FAAM
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From: Morens, David (NIH/NIAID) [E] (b)(6)
Sent: Thursday, 19 August 2021 10:07 PM
To: Jason Gale <j.gale@bloomberg.net>; (b)(6) ; (b)(6) ; Wang Linfa (b)(6) ; Garry, Robert F (b)(6)
Subject: RE: (BN) SARS Survivors Offer Clues on Protecting Against Future Scourges

- External Email -

Yes, hugely important, congrats to Linfa! This was the paper you mentioned a couple weeks back and I've been keenly waiting to see it. Even better than expected. I think many wwill be surprised, which reminds us that assumptions we

might make from other viruses like flu, flaviviruses, etc., might not be germane to sarbecoviruses….

David

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From: Jason Gale (BLOOMBERG/ NEWSROOM:) <j.gale@bloomberg.net>
Sent: Wednesday, August 18, 2021 7:43 PM
To: (b)(6); Morens, David (NIH/NIAID) [E]
(b)(6)
(b)(6) Garry, Robert F (b)(6)
Subject: (BN) SARS Survivors Offer Clues on Protecting Against Future Scourges

Make sure you check out Linfa's cool paper in NEJM today https://www.nejm.org/doi/full/10.1056/NEJMoa2108453?query=featured_home

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SARS Survivors Offer Clues on Protecting Against Future Scourges
2021-08-18 21:00:00.0 GMT

By Jason Gale
(Bloomberg) -- A serendipitous discovery in survivors of the 2003 SARS outbreak offers important clues about how next-generation vaccines might counter dangerous coronavirus variants now and protect against future pandemics.
The signs were found in the blood of people who contracted the virus that causes severe acute respiratory syndrome, or SARS, almost 20 years ago. Survivors who recently received two shots of Pfizer Inc.'s Covid-19 vaccine developed antibodies that not only blocked the current virus and its variants, they countered related pathogens that could spawn future outbreaks.
"That was really, really unexpected, but an important discovery," said Linfa Wang, a professor of virology at Singapore's Duke-NUS Medical School and the lead author of the paper that compared the immune responses of different patient groups. The findings were published Thursday in the New England Journal of Medicine.
Wang is working on experimental vaccines based on SARS that could bolster the immunity generated by current Covid shots to protect against a broader array of SARS-CoV-2 variants and their virological cousins. That includes so-called sarbecoviruses sometimes carried by bats, pangolins, civets and other wildlife -- all potential vectors for novel infections in humans.
Read More: Delayed Wuhan Report Adds Crucial Detail to Covid Origin Puzzle
"Based on our data, there is a glimpse of hope that now we can really develop an efficient pan-sarbecovirus vaccine," which would protect against an array of infections, Wang said over Zoom. "For the first time, maybe we can do something in the context of pandemic preparedness."

Prime Boost

More research is underway to understand how sequential vaccination is able to prime the immune system and then boost its response to defend against sarbecoviruses, Wang said. He hopes patient studies on the new shots will begin this year or next.
In addition, the potent infection-fighting antibodies produced by Covid-vaccinated SARS survivors may provide the

basis for treatments known as monoclonal antibodies, Wang said. They will be studied further and, if successful, could be stockpiled to provide rapid treatment for patients infected with newly emerging sarbecoviruses, he said.

The research builds on technology developed by Wang and his colleagues that lets scientists identify the specific coronavirus strains that triggered production of their antibodies. In this way, a simple blood test could determine within an hour what variant a Covid-19 patient was infected with, Wang said. The antibody analysis technique could also be used to identify early cases of Covid-19 and potentially the progenitor of SARS-CoV-2, he said.

The study was supported by grants from the Singapore National Research Foundation and National Medical Research Council.

To contact the reporter on this story:
Jason Gale in Melbourne at j.gale@bloomberg.net
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Brian Bremner at bbremner@bloomberg.net
Michelle Fay Cortez, Jason Gale

To view this story in Bloomberg click here:
https://blinks.bloomberg.com/news/stories/QY0NH0DWRGG1

From: Morens, David (NIH/NIAID) [E]
Sent: Tue, 5 Oct 2021 11:33:41 +0000
To: Taubenberger, Jeffery (NIH/NIAID) [E] ((b)(6)); Peter Daszak ((b)(6)); Keusch, Jerry ((b)(6)); Rich Roberts ((b)(6))
Subject: Collins retiring... FW: NIH director's move, questions about Merck's new Covid pill, & rural hospital puts telehealth to the test

David

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From: STAT | Morning Rounds <newsletter@statnews.com>
Sent: Tuesday, October 5, 2021 6:01 AM
To: Morens, David (NIH/NIAID) [E] (b)(6)
Subject: NIH director's move, questions about Merck's new Covid pill, & rural hospital puts telehealth to the test

STAT morning rounds

YOUR DAILY DOSE OF NEWS IN HEALTH AND MEDICINE

By Elizabeth Cooney

How do you make health care accountable? That's up for discussion at 1 p.m. ET today during a STAT+ Conversation with Farzad Mostashari, CEO and co-founder of Aledade, and STAT's Nicholas St. Fleur. STAT+ subscribers can join here.

NIH leader to announce retirement today

NIH DIRECTOR FRANCIS COLLINS. (GRAEME JENNINGS/AP)

Francis Collins, the pioneering genetics researcher and longtime director of the National Institutes of Health, will announce his retirement from the agency today, two sources told STAT. His departure, first reported last night by Politico, marks the end of an era for the $40 billion government research agency. He has worked at the NIH since 1993, and was nominated to serve as director in 2009 by President Obama. An evangelical Christian with a medical degree and Ph.D. in physical chemistry, Collins, 71, is among the most revered political figures in Washington — so much so that President Trump and President Biden, upon their elections, each chose to reappoint him to lead the agency. Read more.

We have questions about Merck's new Covid pill

Last Friday's announcement that a pill from Merck and partner Ridgeback Biotherapeutics kept Covid patients out of the hospital made headlines and moved stocks. But as is so often true when data are released by press release, there are still many questions left unanswered. STAT's Matthew Herper takes up some of them:

- How many other anti-Covid pills will end up proving effective?
- How safe is molnupiravir?
- Will molnupiravir be used only in unvaccinated patients?
- What will it cost and who will pay?
- How will the availability of Covid pills affect vaccines and other treatments?

Spoiler: Matt also asks how this treatment relates to ivermectin. "This is simple: it doesn't. But it's worth taking a look at what data are available for each." Read more.

'Information alone is not enough,' new leader of Jackson Heart Study asserts

APRIL CARSON, DIRECTOR OF THE JACKSON HEART STUDY. (COURTESY UNIVERSITY OF MISSISSIPPI MEDICAL CENTER)

The nation's largest and longest-running study of cardiovascular disease in African Americans calls Jackson, Miss., home. That community, like others in the southeastern U.S., has long experienced disproportionately high rates of cardiovascular disease. April Carson, an epidemiologist who just became the Jackson Heart

Study's new director, talked with me recently about her new role.

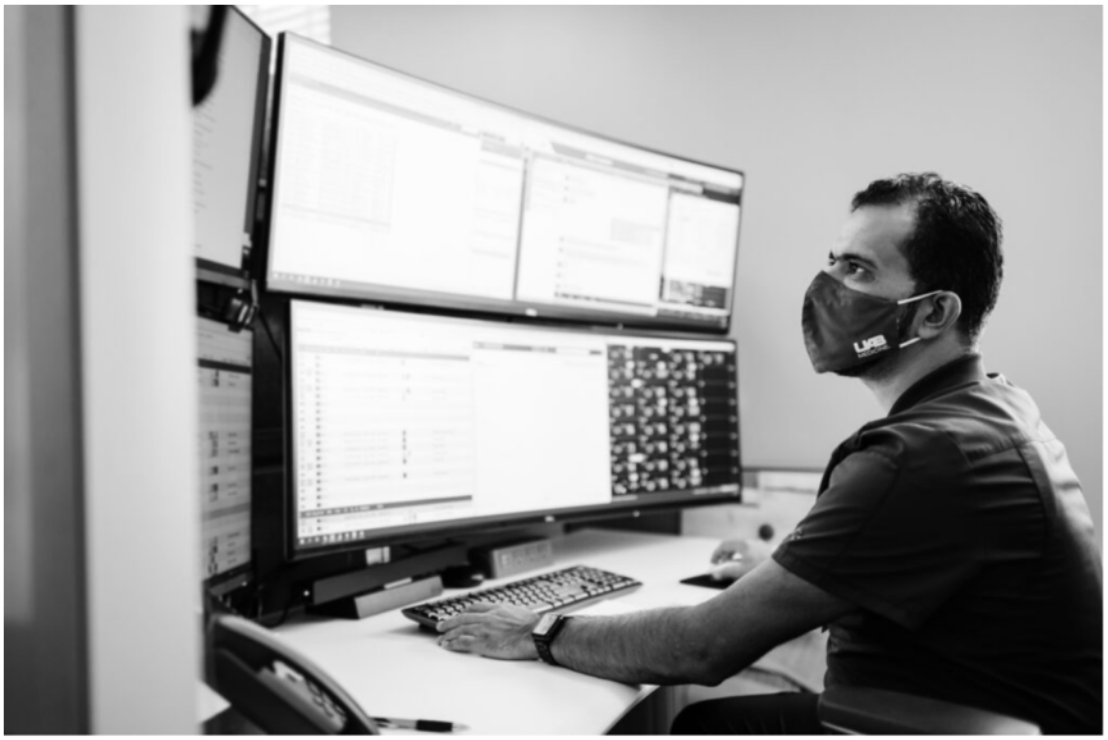
How do you see the study's mission?
Research is important to provide us with information, but information alone is not enough. We know there are disparities in health outcomes. But what can we do about it?

What is your vision for success?
I would love to see the Jackson Heart Study be a leader in preventing the occurrence of cardiovascular risk factors. In an ideal world, that's Mississippi having the lowest problems of hypertension, Mississippi really making strides in the prevention of cardiovascular risk factors.

You can read the full interview here.

options is senior-focused primary care, explained here by Reneé Buckingham, leader of Humana-owned CenterWell Senior Primary Care and Conviva Care Solutions.

Inside STAT: Telehealth gave a rural Alabama hospital a lifeline. Then the pandemic hit



AT UAB, DOCTORS AND NURSES WORK OUT OF A NEW OPERATIONS CENTER, SUPPORTING THE HOSPITAL'S TELE-ICU. (UNIVERSITY OF ALABAMA AT BIRMINGHAM)

On the surface, there's nothing about Whitfield Regional Hospital that would make it a safety net for the sickest Covid-19 patients. It has a small ICU with only eight beds, and no critical care doctors on

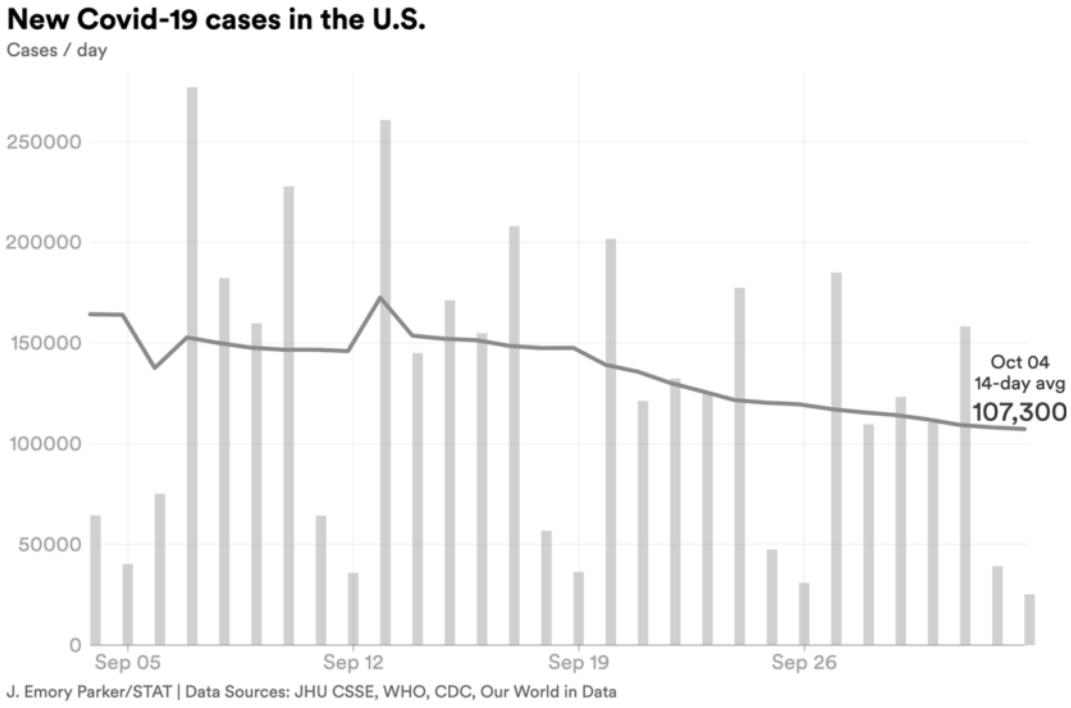
staff. The rural hospital has spent decades focused on caring almost exclusively for the community surrounding Demopolis, Ala., population 7,000, in the heart of the state's Black Belt. But over the summer, Whitfield became an unlikely landing pad for critically ill Covid-19 patients from across the entire state — with the help of a team of telemedicine specialists calling in from more than 100 miles away. STAT's Katie Palmer explains how that ICU's outsized role in Alabama's critical care is a contortion borne of the pandemic.

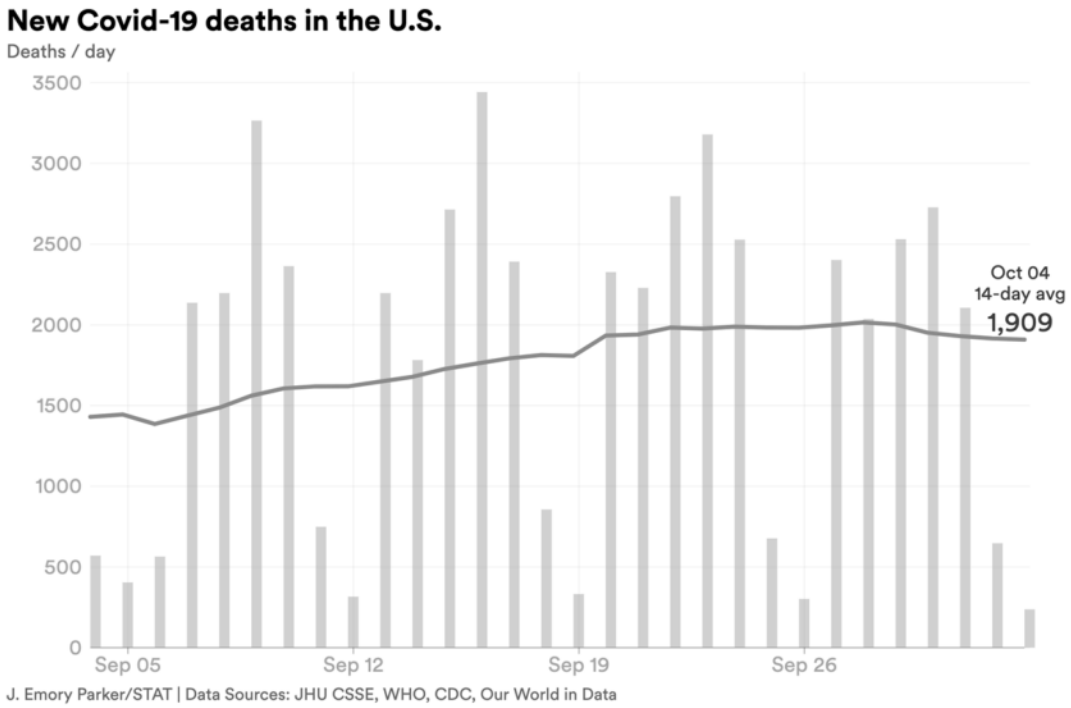
Proof of hope: Jolts from a brain implant provided relief to one severely depressed person

It's just one patient, but her one laugh is inspiring cautious optimism. Last year Sarah, 36 years old and severely depressed (and who chose to only reveal her first name publicly), sat down in a lab with a head full of surgically implanted sensors. After a subtle electrical shock deep in her brain interfered with the dark spirals her depression had sent her on since she was a child, she laughed. Here's how it works: By mapping out a depressed patient's brain circuitry, researchers were able to identify biological markers that told them symptoms were coming, and implant a device to deliver targeted electrical stimulation and provide immediate relief in something like a cranial call and response. Now researchers want to see if they can recreate her experience. STAT's Isabella Cueto has more.

Lacks family sues biotech over use of her cells

Henrietta Lacks died of cervical cancer in a Baltimore hospital decades ago, but her cells — the first human cells to be successfully cloned — live on in laboratories around the world, and have helped develop the polio vaccine, genetic mapping, and Covid-19 vaccines. Her story of tumor tissue being taken without her consent is behind Rebecca Skloot's book "The Immortal Life of Henrietta Lacks" and an HBO movie starring Oprah Winfrey. Now a lawsuit, filed yesterday, 70 years after her death on Oct. 4, 1951, seeks profits made from her cell by Thermo Fisher Scientific, of Waltham, Mass., saying the biotech company knowingly mass produced and sold tissue taken from Lacks by doctors at Johns Hopkins Hospital. Thermo Fisher did not immediately comment on the lawsuit, the Associated Press said in its story.


New Covid-19 cases in the U.S.
Cases / day
250000
200000
150000
100000
50000
0
Sep 05
Sep 12
Sep 19
Sep 26
Oct 04
14-day avg
107,300
J. Emory Parker/STAT | Data Sources: JHU CSSE, WHO, CDC, Our World in Data



What to read around the web today

- First they targeted generic drugs. Now a group of hospitals wants to build a better digital health marketplace. STAT+
- Covid precautions put more prisoners in isolation. It can mean long-term health woes. NPR
- 20 years after the anthrax attacks, we're still unprepared. Wired

- Losing your hair? You might blame the great stem cell escape. New York Times
- I didn't know my Mom was dying. Then she was gone. The Atlantic

Thanks for reading! More tomorrow,

@cooney_liz

HAVE A NEWS TIP OR COMMENT?

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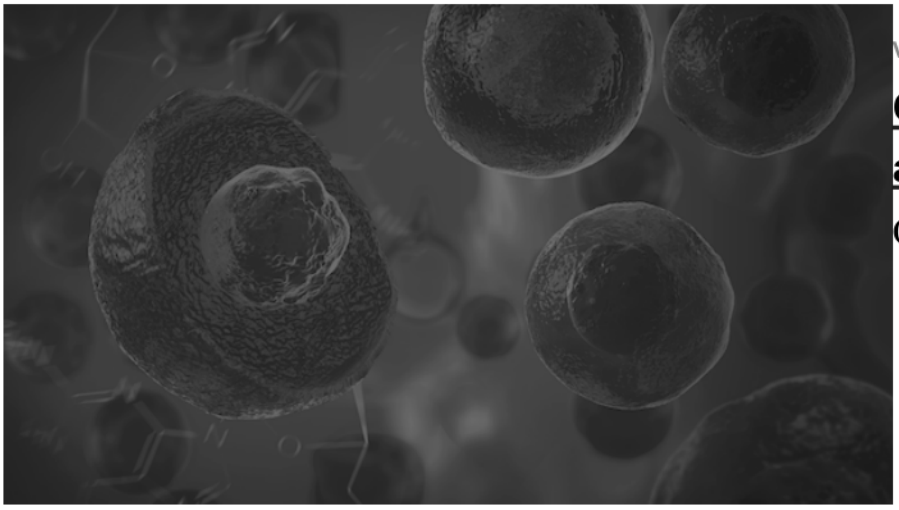
STAT SUMMIT

2021 STAT Summit

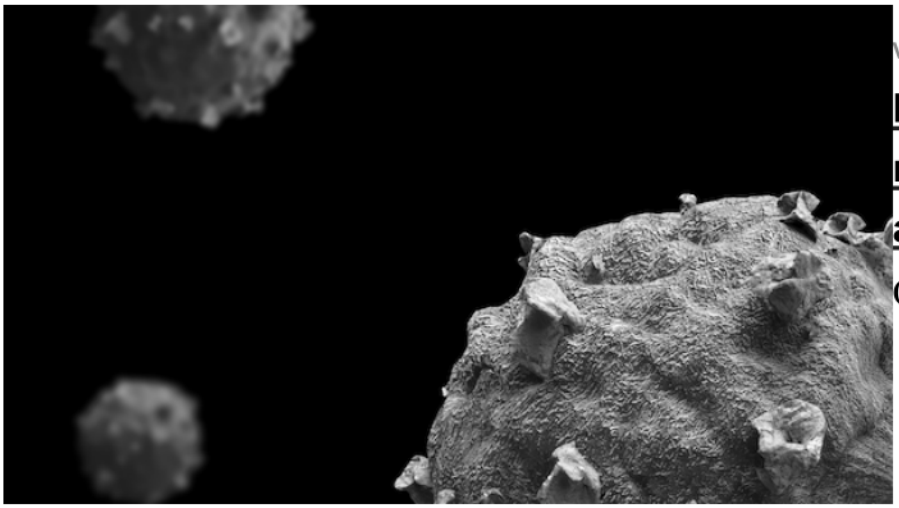
Nov. 16 - 18



VIDEO CHAT

CAR-T com age?

Oct. 14



VIDEO CHAT

Bispecifics: next weapo against can

Oct. 28

Tuesday, October 5, 2021

STAT

From: Morens, David (NIH/NIAID) [E]
Sent: Wed, 23 Jun 2021 16:53:42 +0000
To: Peter Daszak; Keusch, Jerry; Rich Roberts
Subject: RE: Interview request: CNN / Jesse Bloom preprint

I discussed this very Q with Jeff T this morning, and he felt yes, deleting incomplete data in a larger dataset with complete data, in the context of having no reason to suspect some bias, is a normal approach. Certainly we do that in epi all the time, use only the "completely complete" data as the best and most honest way to present data.

David

David M. Morens, M.D.
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Senior Advisor to the Director
Office of the Director
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Building 31, Room 7A-03
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Bethesda, MD 20892-2520
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301 496 4409
(b)(6)

From: Peter Daszak (b)(6)
Sent: Wednesday, June 23, 2021 12:05 PM
To: Morens, David (NIH/NIAID) [E] (b)(6); Keusch, Jerry (b)(6); Rich Roberts (b)(6)
Subject: RE: Interview request: CNN / Jesse Bloom preprint

It's just sad that the press stories around this are not about how this adds to our information on origins (or not), but about how it looks to some people that Chinese scientists are corrupt and involved in a cover-up.

Of course, even scientists who don't regularly upload gene sequences (e.g. like me) don't really know whether what they did by removing them was normal or abnormal, and this is what these stories rely on – so complicated an issue that it just will continue a narrative that's already being amplified.

I'm trying to get others ((b)(6)) to comment on whether it would be normal to delete partial genomes because you think they might not be high quality. Maybe they already had a bunch of full genomes and didn't see great value in adding more partial sequences that could be incorrect, particularly when it didn't change the conclusions much. But, I just don't know …

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance

520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b)(6)
Website: www.ecohealthalliance.org
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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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Jennifer Routh [E]
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National Institute of Allergy and Infectious Diseases (NIAID)

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Subject: Interview request: CNN / Jesse Bloom preprint
Importance: High

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CNN
Maggie.Fox@cnn.com; (b)(6)
Topic: Jesse Bloom's analysis of early SARS-CoV-2 genetic data
Deadline: Today

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Subject: FW: Jesse Bloom and missing SARS-Cov2-2 genetic sequences
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Thanks,
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Cc: Fine, Amanda (NIH/OD) [E] (b)(6); Burklow, John (NIH/OD) [E] (b)(6); Wojtowicz, Emma (NIH/OD) [E] (b)(6); Brodd, Lauren (NIH/OD) [E] (b)(6)
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I am pretty certain NIH is going back over what he has pointed out.

Can someone please help me, even on background? Thank you!

Maggie Fox
Senior Editor, Health
CNN

On Jun 23, 2021, at 08:36, Myles, Renate (NIH/OD) [E] (b)(6) wrote:

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Thanks much,
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Hi y'all-
Jesse Bloom, geneticist at Fred Hutchinson Cancer Center, published this preprint and has been all over Twitter tonight saying early sequences of coronavirus samples from Wuhan were somehow deleted from the NIH database. He says Dr Collins confirmed this and was helping him track it down?
https://www.biorxiv.org/content/10.1101/2021.06.18.449051v1.full.pdf

Can you all confirm this and may I speak to Dr. Collins about it?

Thank you so much!

Maggie Fox
Senior Editor, Health

CNN
(b)(6)

Disclaimer

From: Morens, David (NIH/NIAID) [E]
Sent: Wed, 23 Jun 2021 17:39:26 +0000
To: Peter Daszak; Keusch, Jerry; Rich Roberts
Subject: RE: Jesse Bloom preprint

I have heard similar comments from a different source….

David

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Sent: Wednesday, June 23, 2021 1:34 PM
To: Morens, David (NIH/NIAID) [E] (b)(6); Keusch, Jerry (b)(6); Rich Roberts (b)(6)
Subject: RE: Jesse Bloom preprint
Importance: High

Here are some (confidential) comments from a leading bioinformatician in a leading international virology group (not China):

"My conclusion is that the authors might have found some "obvious" sequencing errors and decided to withdraw them. You should know that:

> The authors are mostly doctors, not scientists, and seem to be unexperienced in this area of work
> They used Nanopore sequencing, which is not very reliable. We use it to get "draft" sequences
> Bloom did state the NCBI's position is that withdrawal can't be done by authors and has to be done by NCBI. My guess will be: NCBI thinks it is "nothing unusual". This is not what Bloom wrote in this paper"

Cheers,

Peter

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Sent: Mon, 26 Jul 2021 14:20:39 +0000
To: Peter Daszak; Keusch, Jerry
Subject: RE: Science Speaks: Clues to COVID origins via Wuhan wet market study 2017-2019 of severe fever with thrombocytopenia syndrome

Every team meeds a professional clown

David

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Subject: RE: Science Speaks: Clues to COVID origins via Wuhan wet market study 2017-2019 of severe fever with thrombocytopenia syndrome

Yes – thanks to him for 'man-splaining' how this work may or may not be possible to do!

No doubt this will form part of his application to join the WHO phase 2 team as US uber-investigator-General….

Cheers,

Peter

Peter Daszak
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Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Morens, David (NIH/NIAID) [E] (b)(6)
Sent: Monday, July 26, 2021 10:05 AM
To: Peter Daszak ((b)(6)) (b)(6); Keusch, Jerry ((b)(6)) (b)(6)
Subject: FW: Science Speaks: Clues to COVID origins via Wuhan wet market study 2017-2019 of severe fever with thrombocytopenia syndrome

From Uncle Dan Lucey…..

David

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From: Folkers, Greg (NIH/NIAID) [E] (b)(6)
Sent: Sunday, July 25, 2021 6:13 PM
Subject: Science Speaks: Clues to COVID origins via Wuhan wet market study 2017-2019 of severe fever with thrombocytopenia syndrome

Science Speaks: Global ID News

Clues to COVID origins via Wuhan wet market study 2017-2019 of severe fever with thrombocytopenia syndrome

July 15, 2021.

By Daniel R. Lucey MD, MPH, FIDSA

Retrospective testing for SARS-CoV-2 virus and antibody could be (or has been) done using blood and other samples highly likely to have been obtained from the 18 mammalian species (including masked palm civet, racoon dogs, and mink) reported in the Wuhan wet markets, May 2017-November 2019, as part of a study on "Severe Fever with Thrombocytopenia (SFTS)" published not until June 7, 2021.

Photos from the Wuhan Huanan seafood market include racoon dogs, hedgehogs, bamboo rats, and badgers with the description of **"Poor welfare of animals on sale in Huanan seafood market."**

A tick found on a hedgehog is emphasized in the legend to Figure 2, given that ticks are thought to be the main transmission route from animals to humans of the bunyavirus first discovered in a 2009 outbreak in Hubei and Henan provinces of Severe Fever with Thrombocytopenia Syndrome. (An aerosol route is less commonly implicated in nosocomial, familial, and other cases of persons-to-person transmission of this bunyavirus causing SFTS).

Although *not explicitly stated* in this June 7 paper in *Nature*, it is highly likely that samples of blood and perhaps respiratory and other types of samples from the animals surveyed on a monthly basis in Wuhan wet markets from May 2017-November 2019 would have been obtained.

In addition, blood samples from humans working in these wet markets, including the Wuhan Huanan seafood market, would very likely have been obtained to test for bunyavirus and antibody to the bunyavirus that causes SFTS. (Less likely, even respiratory samples from humans may have been obtained).

Such samples from both animals and humans in the Wuhan wet markets could be tested for antibody to SARS-CoV-2, as well as any respiratory samples for SARS-CoV-2 itself, month-by-month over 30 months from May 2017-November 2019.

If antibody-negative results were demonstrated in 2017 and 2018, followed by some antibody (and perhaps virus)-positive results in 2019, **then a "look back" retrospective study of the supply chain of animals and the epidemiology of the humans could provide clues to the COVID origins in terms of emergence timeline, geography, animal species, and human infections.**

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From: Morens, David (NIH/NIAID) [E]
Sent: Wed, 28 Jul 2021 15:36:04 +0000
To: Keusch, Gerald T; Peter Daszak
Cc: Robert Kessler; Sturchio, Jeff
Subject: RE: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

Very well said, and let me add that if i=t seems appropriate please tell these types of reporters I can talk to them off the record or on background….

David

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From: Keusch, Gerald T (b)(6)
Sent: Wednesday, July 28, 2021 11:04 AM
To: Peter Daszak (b)(6); Morens, David (NIH/NIAID) [E] (b)(6)
Cc: Robert Kessler (b)(6); Sturchio, Jeff (b)(6)
Subject: RE: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

I followed up with Simone today, as I am sure she will continue to write about this. Here's what I said – reading it again I really like my last line, which Peter has noted is probably the only thing people take away from articles they are reading.

"Thanks for the article. Sorry I was unavailable the past several days, as I was away and off line.

The issues you are covering are important. I believe the key is to establish a level playing field in which all countries have a stake in cooperating to figure out how CoV-2 entered the human population. This takes a level of diplomatic finesse that seems to be in short supply, and I would finger three entities at the top of my list in alphabetical order, China, the USA, and WHO. The only way this can succeed is to have the political community agree this needs to be done and then to step back and empower the scientific community – especially including internationally respected scientists in China and around the world who both know and trust one another because they have developed personal relationships and collaborations over multiple years – to proceed ahead without interference. I would go so far as to say there is no other way. Power, partisanship, playing to domestic audiences, and provocative language will accomplish nothing, and the whole world will suffer for it. "

From: Peter Daszak (b)(6)
Sent: Wednesday, July 28, 2021 10:47 AM
To: Keusch, Gerald T (b)(6); Morens, David (NIH/NIAID) [E] (b)(6)
Cc: Robert Kessler (b)(6); Sturchio, Jeff (b)(6)
Subject: RE: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

Yes – I spoke with her off the record. She quotes me as 'someone with direct knowledge of the WHO work in Wuhan' or something.

Jerry's also quoted.

It's good to see a lot of the BS getting cleared, but I do think that the WHO DG's blatant politicking is being missed by many of these science-y commentators that are being quoted. A lot of them seem to be completely OK with a new team because, I guess, it gives them a chance to be involved – e.g. Wanda Markotter's comments about the current team being not geographically balanced – what a joke – Vietnam, Japan, Russia, Sudan, NZ – she just didn't bother to actually check if that's correct…

Cheers,

Peter

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President

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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From: Keusch, Gerald T (b)(6)
Sent: Wednesday, July 28, 2021 10:42 AM
To: Morens, David (NIH/NIAID) [E] (b)(6); Peter Daszak (b)(6)
Cc: (b)(6); Sturchio, Jeff ((b)(6)) (b)(6)
Subject: RE: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

I love that picture of Tony. I'm attaching something Simone McCarthy just published in the S. China Morning Post. I discovered this morning that she had tried to get in touch with me the past two days, but I was focused on other things and not really looking at my inbox as I focused on my outbox. But she had

something from my prior conversations with her to stick in there regarding the bad decisions at WHO regarding the investigation.

Jerry

From: Morens, David (NIH/NIAID) [E] (b)(6)
Sent: Wednesday, July 28, 2021 10:29 AM
To: Peter Daszak (b)(6)
Cc: Keusch, Gerald T (b)(6); Sturchio, Jeff ((b)(6)) (b)(6)
Subject: RE: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

I wouldn't trust them either, given their history which I didn't know. I'll try to remember to copy Robert K, and ping me if I forget.

Many of these things come from our OD news sweeps, which go on 24-7. But they don't get anywhere near everything, as they are more interested in Ton's press coverage than science itself.

David

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From: Peter Daszak (b)(6)
Sent: Wednesday, July 28, 2021 10:10 AM
To: Morens, David (NIH/NIAID) [E] (b)(6); Keusch, Jerry (b)(6)
Cc: Robert Kessler (b)(6); Jeff Sturchio (b)(6)
Subject: RE: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

Thanks for sharing David. Please cc Robert Kessler in on these in case he also misses them. I'm also cc'ing Jeff Sturchio who's working with us to navigate the media attacks at the moment.

This reporter contacted me, and I refused to talk, even though I suspected he would do a decent job. I think I'm the person he says 'supports this sort of research but has been worn down by death threats'.

I actually like the tenor of the story – it's factually correct and points out the danger of people like Lipsitch and Ebright using a false premise to support their efforts to re-litigate 'gain of function'. It's good to see Lipsitch having to be factually correct here and agree that Rand Paul massively overstated their case!

One of the reasons I didn't speak with this reporter, by the way is that the journal (The Intercept) is one of the orgs that's FoIA'd 38 of EcoHealth's NIH grants and annual reports going back to 2001– just wasn't sure I could trust their motives!

Cheers,

Peter

Peter Daszak

President

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From: Morens, David (NIH/NIAID) [E] (b)(6)
Sent: Wednesday, July 28, 2021 9:55 AM
To: Peter Daszak ((b)(6)) ; (b)(6) ; Keusch, Jerry ((b)(6)) (b)(6)
Subject: FW: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

David

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From: Folkers, Greg (NIH/NIAID) [E] (b)(6)
Sent: Tuesday, July 27, 2021 2:48 PM
Subject: The Intercept: Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research https://bit.ly/3iR7zHP

At a Senate hearing on July 20, 2021, Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, told Sen. Rand Paul that he resented the suggestion that he had lied to Congress. Photo: J. Scott Applewhite/Pool/AFP via Getty Images

Rand Paul's Attack on Anthony Fauci Chills Scientific Debate Over Gain-of-Function Research

By politicizing the debate over virus-modifying research, the senator has thrilled conservatives but discouraged scientists from weighing in.


Robert Mackey
July 27 2021, 10:14 a.m.

A decadelong debate over pandemic preparedness that has divided some of the world's leading biologists into opposing camps, for and against so-called gain-of-function research — in which deadly pathogens that could cause pandemics are artificially enhanced for study in the lab — has all but ground to a halt in the past week, thanks to Sen. Rand Paul.

That's because the Republican senator from Kentucky politicized the argument last week, by cherry-picking expert opinions from critics of the research who call it too risky to pursue, to publicly accuse Dr. Anthony Fauci of lying to Congress, when he said that his National Institute of Allergy and Infectious Diseases had never funded gain-of-function studies at the Wuhan Institute of Virology in China.

Paul's made-for-television broadside against Fauci thrilled Fox News hosts and colleagues like Rep. Jim Jordan, the Ohio Republican who has also pushed the debunked conspiracy theory that research financed by Fauci's agency, which some experts describe as gain-of-function, could have led to the development of SARS-CoV-2, the deadly coronavirus that causes the disease Covid-19, in the Wuhan lab.

Fauci rejected Paul's claim that research carried out in Wuhan before 2017 with some support from the NIAID met the definition of gain-of-function and pointedly explained that it was impossible to make SARS-CoV-2 from the coronavirus used in that study.

Almost as soon as the heated exchange concluded, the senator's staff uploaded a truncated version of the video on his YouTube channel under the headline, "Dr. Fauci Caught Lying about NIH Funding in Wuhan."

That video was edited by Paul's staff so that it ends before Fauci responded to the senator's harangue by saying, "I totally resent the lie that you are now propagating, senator, because if you look at the viruses that were used in the experiments … it is molecularly impossible … to result in SARS-CoV-2."

On social networks, Republican operatives unconcerned with the facts — like Richard Grenell, the Twitter troll who served as Donald Trump's director of national intelligence for three months — cheered on Paul's attack.

But Paul's false claim that Fauci's supposed support for gain-of-function studies gave him "responsibility for 4 million people dying around the world from a pandemic," and the ensuing frenzy in the conservative media, also caused some previously outspoken biologists who have made the case against such experiments to fall silent.

In the wake of Paul's attack on Fauci, several prominent scientists who question the wisdom and safety of gain-of-function experiments — in which biologists deliberately create pandemic-causing pathogens in the lab in order to better prepare to combat them should they evolve in nature — refused to speak to me on the record. One after another, they said Paul's patently false claim that Fauci was to blame for the pandemic, and his selective outrage at gain-of-function research only when conducted in China, made it all but impossible for them to say anything about the pre-pandemic experiments in Wuhan without being vilified by partisans.

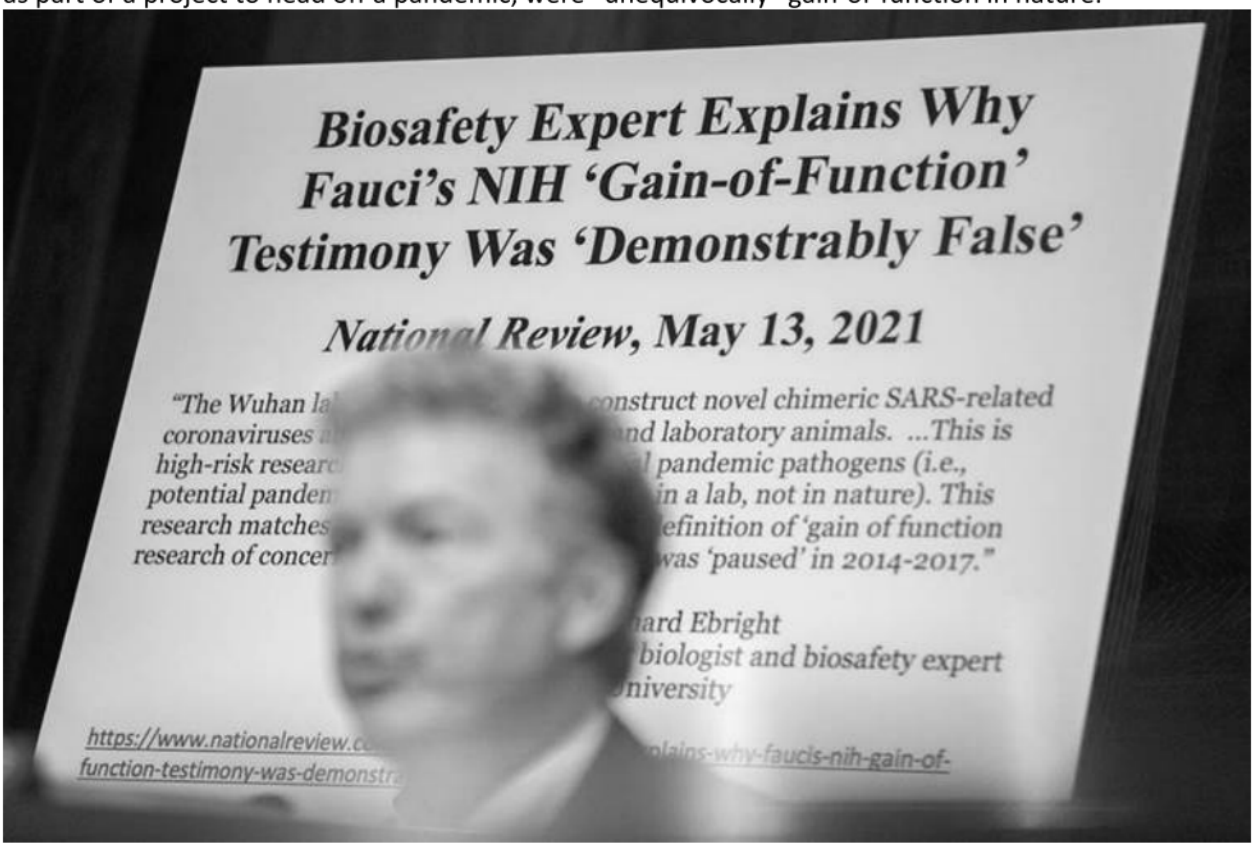
One biologist who supports such research told me that he would have liked the opportunity to correct what he called misinformation about the experiments, but had been worn down by death threats.

To recap, at a hearing in May, Paul first accused Fauci of having supported gain-of-function research in Wuhan, which the senator, who is also a doctor, misleadingly defined as "experimenting to enhance the coronavirus's ability to infect humans." In fact, the coronavirus that researchers experimented on between 2014 and 2017 at the Wuhan Institute, with some financial support from the NIAID, was from a strain found in bats that is not closely enough related to SARS-CoV-2 to have been used to fabricate the virus that causes Covid-19 in a lab.

Fauci also insisted that his agency, which is part of the National Institutes of Health, had never funded gain-of-function research in Wuhan.

When Fauci returned to the senate committee last week, Paul confronted him with the words of Richard Ebright, a molecular biologist at Rutgers University and a longtime critic of gain-of-function studies, who told the conservative magazine National Review that Fauci's testimony in May was "demonstrably

false," since, in Ebright's opinion, the experiments at the Wuhan Institute, indirectly funded by the NIAID as part of a project to head off a pandemic, were "unequivocally" gain-of-function in nature.



Sen. Rand Paul, a Kentucky Republican, used a visual aid to accuse Dr. Anthony Fauci of lying to Congress during a Senate Health, Education, Labor, and Pensions Committee hearing on July 20, 2021.
Photo: Stefani Reynolds-Pool/Getty Images

Fauci insisted that the biologist Paul cited was simply wrong, saying experts at the National Institutes of Health had evaluated the Wuhan project and concluded that the experiments there did not meet the criteria for gain-of-function research used by the United States government.

The exchange between Paul and Fauci got even more heated when the senator seemed to imply that this research funded by Fauci's agency could have led to the development of SARS-CoV-2, the deadly coronavirus that causes Covid-19, in the Wuhan lab.

As Fauci correctly noted, that speculation was wildly misleading, since it was "molecularly impossible" for the type of coronavirus used in the pre-2017 experiments to have been manipulated in the lab to create SARS-CoV-2.

On that point, even some of the most outspoken critics of gain-of-function research on potential pandemic pathogens agree with Fauci. Kevin Esvelt, an MIT biologist who told PolitiFact in May that the experiments conducted in the Wuhan study should be considered gain-of-function also emphasized that those experiments "definitely did NOT lead to the creation of SARS-CoV-2."

(Esvelt, who worries that viruses developed through gain-of-function experiments in a lab could one day be used as weapons, told "The Open Mind" on PBS in March that whether the virus that caused the Covid-19 pandemic came from an animal or came from a lab, "it was not designed to be a weapon — because anyone good enough to make this thing could make a more devastating weapon.")

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Paul was also rebuked in May by Marc Lipsitch, a microbiologist and professor of epidemiology at Harvard University who brought together hundreds of scientists and experts in law and ethics in 2014 to call for amoratorium on gain-of-function experiments that could create highly transmissible, novel strains of dangerous viruses in laboratories.

Lipsitch wrote in a Twitter thread that in his attack on Fauci in May, Paul had "FALSELY" claimed that the working group Lipsitch assembled had "characterized work at the Wuhan Institute of Virology as gain-of-function." While he and many members of the working group "support proper investigation of SARS-CoV-2 origins including the lab leak hypothesis and continue to oppose many forms of GOF research," he added, "it is just fabrication to say we have made any statement as a group about work in Wuhan."

Fauci did not get a chance to explain during the hearing what the scientific basis was for the determination by NIAID biologists that the experiments conducted at the Wuhan Institute of Virology, described in a paper published in 2017, were not subject to a temporary pause on the funding of gain-of-function research imposed during the Obama administration in 2014, which was lifted in 2017 after Trump became president.

But in a statement provided to The Intercept on Monday, NIAID explained the reasoning behind its review of the experiments conducted at the Wuhan Institute on behalf of EcoHealth Alliance, a nonprofit in New York that works with researchers in China to study viruses that have the potential to jump from bats to humans. The agency wrote that its scientists had concluded the pre-2017 experiments in Wuhan were not barred by the temporary pause on gain-of-function research, "because they were not reasonably expected to increase transmissibility or virulence of these viruses in humans."

"Under the grant, EcoHealth Alliance proposed research to create chimeric viruses by placing a small portion of newly identified, evolutionarily distant, bat coronaviruses into another well characterized bat coronavirus that has never been demonstrated to infect humans called WIV1," NIAID wrote. "The purpose of this work was to examine whether the newly discovered viruses were able to use the human ACE2 receptor like WIV1 and other SARS-related coronaviruses already do. In the context of these experiments, this well-characterized bat coronavirus would be considered the parental strain against which the function of the new chimeric viruses would be assessed. With this comparison, the newly created chimeric viruses did not gain any function relative to the parental strain; the chimeric viruses did not replicate in cell culture any better than the parental WIV1. In addition, research that had been published in peer-reviewed scientific journals demonstrated that viruses similar to those proposed under the grant had reduced pathogenicity as compared to the parental viruses. For these reasons, it was not reasonably anticipated that the viruses involved in research under the grant would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route, and therefore did not meet the criteria for gain-of-function research described in the research funding pause."

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