From: <u>noreply@salesforce.com</u> on behalf of <u>ASPA StEP</u>

To: NIAID Media Inquiries; NIAID COGCORE; Fritz, Craig (NIH/OD) [E]; Fine, Amanda (NIH/OD) [E]; Myles, Renate

(NIH/OD) [E]; Deatrick, Elizabeth (NIH/NIAID) [E]; Polimeni, Lydia (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD)

[E], Roberts, Jacqueline (NIH/OD) [E], Akinso, Woleola (NIH/OD) [E]

Subject: StEP Media Inquiry NIAID - Gain of Function research, Fact Check - ref:500t0000000GwoeAAC

Date: Friday, July 23, 2021 4:00:00 PM

A new or updated media inquiry has been submitted for your review. Click on the link at the bottom of this email to open the inquiry in StEP. Reply all to this email if you have questions or feedback on this inquiry. Once you have completed your review in the system, select "Submit to ASPA" to send the inquiry for ASPA review. If ASPA review is not required, change the status of the inquiry to "Ready to Publish" to close out your review.

.....

ASPA StEP Number: 00004646

Reporter / Interviewer: Lori Robertson

Media Outlet: Fact Check

Reporter contact information: lori.robertson@factcheck.org

Subject: Gain of Function research

Deadline: Fri Jul 23 16:51:05 EST 2021

Inquiry:

I'm writing about the exchange Dr. Fauci and Sen. Paul had yesterday over whether the NIH funded gain-of-function research in Wuhan. We have written about the issue before, and we have quoted this statement from NIAID on the EcoHealth grant:

The NIAID told the Wall Street Journal: "The research by EcoHealth Alliance, Inc. that NIH funded was for a project that aimed to characterize at the molecular level the function of newly discovered bat spike proteins and naturally occurring pathogens. Molecular characterization examines functions of an organism at the molecular level, in this case a virus and a spike protein, without affecting the environment or development or physiological state of the organism. At no time did NIAID fund gain-of-function research to be conducted at WIV."

Would you be able to provide more information specifically about the 2017 paper Paul cited and why that research would not be considered gain-of-function by the NIH/NIAID? In 2014, the Obama White House said the pause in GOF research would apply to: "gain-of-function research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route." Does the 2017 paper not meet that definition because of the "respiratory route" specification, or is it that the experiments were not anticipated to generate viruses with increased transmissibility to mammals/humans?

Proposed Response/Driving Event:

We would like to respond with the following statement, attributable to NIAID:

"Good afternoon,

Thank you for your inquiry. The experiments conducted at the Wuhan Institute of Virology as described in the 2017 Plos Pathogens paper were supported indirectly by NIAID under a subaward from EcoHealth Alliance.

NIAID reviewed the grant under the <u>U.S. Government Gain-of-Function Deliberative Process</u> and Research Funding Pause of Selected Gain-of-Function Research Involving Influenza. <u>MERS and SARS Viruses</u>. A detailed staff review determined the research proposed under the grant did not meet the criteria for gain-of-function research described in this policy.

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. 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.

NIAID subsequently reviewed this grant under the <u>U.S. Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS P3CO Framework).</u> Again, a detailed staff review determined that the experiments described in the grant were not subject to the HHS P3CO Framework, because they were not reasonably expected to increase transmissibility or virulence of these viruses in humans.

None of the studies proposed under this grant were designed to manipulate the viruses in a

way that would increase their transmissibility or pathogenicity, and no NIAID funding was approved to support gain-of-function research at the Wuhan Institute of Virology, as defined by United States Government criteria. For more information, please see the digital media kit Gain-of-Function Research Involving Potential Pandemic Pathogens."

Additional Information:

This is the first of several such inquiries along these lines; our response was designed so that it might be repurposed to send to other reporters with almost identical questions. This response has been vetted by NIAID SMEs, NIH OCPL, and NIH OGC

Press Officer / Contact Name: Elizabeth Deatrick
Inquiry Type: Media Inquiry
Topics: COVID-19
Type of Media:
Online

Click <u>here</u> to review this inquiry in StEP.

Note - This email is sent from StEP (Strategic Engagement Platform) via StEPemails@hhs.gov. If you have questions about this inquiry, please contact the StEP Help Desk (StEPHelpdesk@hhs.gov.)

From: Fine, Amanda (NIH/OD) [E]

To: Deatrick, Elizabeth (NIH/NIAID) [E]; OCPLPressTeam
Cc: NIAID OCGR NSWB; NIAID Media Inquiries
Subject: RE: For review: Gain of Function press response

Date: Friday, July 23, 2021 1:53:14 PM

Attachments: Response to FactCheck JR ed ae cb AOF clean ss ae AOF TH1 AOF es2 clean fsc.docx

Hi Flizabeth-

No worries—Given the topic I shared this with our leadership as well and included OGC so will see if they have any concerns. Dr. Collins had the attached suggested edits. His concern is that he wants it to be clear that the review for possible GoF was explicitly carried out.

On the side, Dr. Tabak reached out to Dr. Embry on the following:

does anyone know: did they employ the WIV1 backbone for safety reasons? They know the WIV1 backbone is not pathogenic in humans. There question was just to determine if spike proteins from new isolates were able to infect human cell models. So they create chimeras in a safe backbone – it would make no difference if the non pathogenic virus enters the human cell model or not.

Thanks, Amanda

From: Deatrick, Elizabeth (NIH/NIAID) [E] (b) (6) >

Sent: Friday, July 23, 2021 2:41 PM

To: Fine, Amanda (NIH/OD) [E] (b) (6) >; OCPLPressTeam

<OCPLPressTeam@od.nih.gov>

Cc: NIAID OCGR NSWB < NIAIDOCGRNSWB@mail.nih.gov>; NIAID Media Inquiries

<mediainquiries@niaid.nih.gov>

Subject: RE: For review: Gain of Function press response

Hi Amanda,

I have not shared this with NIH OGC for review—we've been working to get this out as quickly as possible, given the amount of review it has needed—but I can share with them if it would be advisable, under the circumstances.

Best,

Elizabeth

From: Fine, Amanda (NIH/OD) [E] (b) (6)

Sent: Friday, July 23, 2021 2:15 PM

To: Deatrick, Elizabeth (NIH/NIAID) [E] < (b) (6) >; OCPLPressTeam

<<u>OCPLPressTeam@od.nih.gov</u>>

Cc: NIAID OCGR NSWB < <u>NIAIDOCGRNSWB@mail.nih.gov</u>>; NIAID Media Inquiries

<mediainquiries@niaid.nih.gov>

Subject: RE: For review: Gain of Function press response

Thanks Elizabeth. Will get back to you.

Quick question, will you be sharing or have you shared with OGC for review?

Thanks! Amanda

From: Deatrick, Elizabeth (NIH/NIAID) [E] (b) (6) >

Sent: Friday, July 23, 2021 12:51 PM

To: OCPLPressTeam@od.nih.gov>

Cc: NIAID OCGR NSWB < NIAIDOCGRNSWB@mail.nih.gov >; NIAID Media Inquiries

<mediainquiries@niaid.nih.gov>

Subject: For review: Gain of Function press response

Hi OCPL,

Over the last few days, we've received a number of press inquiries regarding Dr. Fauci's exchange with Senator Rand Paul at the recent Senate hearing. Many of the reporters are asking the same question: Why was the research that Sen. Paul cited in the hearing not considered to be gain-of-function research? We've drafted a response to one of these inquiries, from FactCheck.org (with the intent that our statement could also be used to respond to related inquires). Considering the context of these questions, we wanted to make sure you had a chance to review this before we send for clearance.

The question, along with our proposed response, is attached—please let me know if you have any questions or edits.

Best,

Elizabeth Deatrick

Technical Writer-Editor

Office of Communications and Government Relations

National Institute of Allergy and Infectious Diseases (NIAID)

(b) (6)

Please note that I am not a spokesperson for NIAID and should not be quoted as such.

Inquiry: "Would you be able to provide more information specifically about the 2017 paper Paul cited and why that research would not be considered gain-of-function by the NIH/NIAID? In 2014, the Obama White House said the pause in GOF research would apply to: "gain-of-function research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route." Does the 2017 paper not meet that definition because of the "respiratory route" specification, or is it that the experiments were not anticipated to generate viruses with increased transmissibility to mammals/humans?"

Response:



		(b) (5)

From: noreply@salesforce.com on behalf of ASPA StEP

To:

Lemar, Naweed (OS/ASPA); Weber, Mark (HHS/ASPA); Lassiter, Jane (HHS/ASPA); Bradley, Tasha (OS/ASPA); Lovenheim, Sarah (HHS/ASPA); Orton, Kristann (OS/ASPA); Allen, Kirsten (HHS/ASPA); Perez, Luisana (HHS/ASPA); Myles, Renate (NIH/OD) [E]; NIAID Media Inquiries; Tates, Carla (HHS/ASPA); Higgins, Sean (HHS/ASPA); Formoso, Paula (HHS/ASPA); Myrie, Simone (OS/ASPA); Wojtowicz, Emma (NIH/OD) [E]; Roberts, Jacqueline (NIH/OD) [E]; Peck, Joshua (HHS/ASPA); Sams, Ian (HHS/ASPA); NIAID COGCORE; Fine, Amanda (NIH/OD) [E]; Deatrick, Elizabeth (NIH/NIAID) [E]; Polimeni, Lydia (NIH/OD) [E]; Akinso, Woleola (NIH/OD) [E]; Dembner, Zachary (HHS/ASPA); Jones, Kamara (HHS/ASPA); Fritz, Craig (NIH/OD) [E]; Hall, Bill (HHS/ASPA)

Media Inquiry: NIH/NIAID - Gain of Function research, Fact Check - ref:500t0000000GwoeAAC Subject:

Date: Monday, July 26, 2021 8:13:13 AM

A new or updated media inquiry has been submitted to ASPA for review.

• To Approve as is: reply all to this email and type, "Approved" on the first line.

- To Approve with edits: reply all to this email and type Approved on the first line and include "with edits" on the second line.
- To place On Hold: reply all to this email and type, "Hold" on the first line. Click on the link at the bottom of this email to open the inquiry in StEP.
- To Reject: reply all to this email and type, "Reject" on the first line.

ASPA StEP Number: 00004646

Press Officer / Contact Name: Elizabeth Deatrick

Inquiry Type: Media Inquiry

Subject: Gain of Function research

Topics: COVID-19

Deadline: Mon Jul 26 10:00:00 EST 2021

Reporter / Interviewer: Lori Robertson

Media Outlet: Fact Check

Type of Media:

Online

Inquiry:

I'm writing about the exchange Dr. Fauci and Sen. Paul had yesterday over whether the NIH funded gain-of-function research in Wuhan. We have written about the issue before, and we have quoted this statement from NIAID on the EcoHealth grant:

The NIAID told the Wall Street Journal: "The research by EcoHealth Alliance, Inc. that NIH

funded was for a project that aimed to characterize at the molecular level the function of newly discovered bat spike proteins and naturally occurring pathogens. Molecular characterization examines functions of an organism at the molecular level, in this case a virus and a spike protein, without affecting the environment or development or physiological state of the organism. At no time did NIAID fund gain-of-function research to be conducted at WIV."

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Proposed Response/Driving Event:

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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.

NIAID subsequently reviewed this grant under the <u>U.S. Department of Health and Human</u>
<u>Services Framework for Guiding Funding Decisions about Proposed Research Involving</u>
<u>Enhanced Potential Pandemic Pathogens (HHS P3CO Framework)</u>. Again, a detailed staff review determined that the experiments described in the grant were not subject to the HHS P3CO Framework, because they were not reasonably expected to increase transmissibility or virulence of these viruses in humans.

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Additional Information:

This is the first of several such inquiries along these lines; our response was designed so that it might be repurposed to send to other reporters with almost identical questions. This response has been vetted by NIAID SMEs, NIH OCPL, and NIH OGC

For ASPA: Click here to review this inquiry in StEP.

For the Agency: Click <u>here</u> to review this inquiry in StEP.

Note - This email is sent from StEP (Strategic Engagement Platform) via StEPemails@hhs.gov. If you have questions about this inquiry, please contact the StEP Help Desk (StEPHelpdesk@hhs.gov.)

From: Ford, Andrew (NIH/NIAID) [E]

To: Routh, Jennifer (NIH/NIAID) [E]; Selgrade, Sara (NIH/NIAID) [E]; Deatrick, Elizabeth (NIH/NIAID) [E]; Embry,

Alan (NIH/NIAID) [E]; Billet, Courtney (NIH/NIAID) [E]

Cc: NIAID OCGR NSWB; NIAID Media Inquiries; NIAID BUGS; Haskins, Melinda (NIH/NIAID) [E]

Subject: Re: For review again: Response to GoF inquiry from FactCheck.org

Date: Thursday, July 22, 2021 8:47:54 PM

Attachments: Response to FactCheck JR ed ae cb AQF clean ss ae AQF TH1 AQF es[2].docx

Dear All.

The attached version contains additional edits/comments from program staff.

Happy to discuss.

Thanks, Andrew

From: "Routh, Jennifer (NIH/NIAID) [E]" (b) (6)

Date: Thursday, July 22, 2021 at 4:55 PM

To: Sara Selgrade (b) (6), "Deatrick, Elizabeth (NIH/NIAID) [E]"

(b) (6) >, "Embry, Alan (NIH/NIAID) [E]" (b) (6) , "Ford,

Andrew (NIH/NIAID) [E]" (b) (6), "Billet, Courtney (NIH/NIAID) [E]"

(b) (6) >, NIAID BUGS <BUGS@niaid.nih.gov>

Cc: NIAID OCGR NSWB < NIAIDOCGRNSWB@mail.nih.gov>, NIAID Media Inquiries

<mediainquiries@niaid.nih.gov>, "Haskins, Melinda (NIH/NIAID) [E]"

(b) (6) >

Subject: RE: For review again: Response to GoF inquiry from FactCheck.org

I am adding BUGS, Andrew and Courtney to this thread so we are all on the same thread. The original response pulled from cleared language. I'd like to get this finalized ASAP. We really need to move this forward.

Jennifer Routh [E]

News and Science Writing Branch

Office of Communications and Government Relations

National Institute of Allergy and Infectious Diseases (NIAID)

NIH/HHS

31 Center Drive Room 7A17C

Bethesda, MD 20892 Direct: (b) (6) (b) (6)

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From: Selgrade, Sara (NIH/NIAID) [E] (b) (6)

Sent: Thursday, July 22, 2021 4:49 PM

To: Deatrick, Elizabeth (NIH/NIAID) [E] < (b) (6) (6) ; Embry, Alan (NIH/NIAID) [E]

(b)(6)>

Cc: NIAID OCGR NSWB < NIAIDOCGRNSWB@mail.nih.gov>; NIAID Media Inquiries

<mediainquiries@niaid.nih.gov>; Haskins, Melinda (NIH/NIAID) [E] (b) (6) >

Subject: RE: For review again: Response to GoF inquiry from FactCheck.org

Thanks Elizabeth. Some edits for your consideration in the attached. I'm copying Melinda as well for her review.

Defer to Alan on whether DMID should review again.

From: Deatrick, Elizabeth (NIH/NIAID) [E] < (b) (6)

Sent: Thursday, July 22, 2021 4:33 PM

To: Embry, Alan (NIH/NIAID) [E] < (b) (6) >; Selgrade, Sara (NIH/NIAID) [E]

(b)(6) >

Cc: NIAID OCGR NSWB < <u>NIAIDOCGRNSWB@mail.nih.gov</u>>; NIAID Media Inquiries

<mediainquiries@niaid.nih.gov>

Subject: For review again: Response to GoF inquiry from FactCheck.org

Good afternoon,

DMID has reviewed our response to FactCheck.org on GoF research, but recommended that we run the copy past you one more time before moving it forward in the clearance process. Please let me know if you have any notes on the attached clean document.

Best,

Elizabeth Deatrick

Technical Writer-Editor

Office of Communications and Government Relations

National Institute of Allergy and Infectious Diseases (NIAID)

(b) (6)

Please note that I am not a spokesperson for NIAID and should not be quoted as such.



(b) (5)