THOMAS R. CARPER, DELAWARE INUMAS R. CANPER, DE LAWARE MAGGIE HASSAN, NEW HAMPSHIRE KYRSTEN SINEMA, ARIZONA JACKY ROSEN, NEVADA ALEX PADILLA, CALIFORNIA JON CSSOFF, GEORGIA RICHARD BLUMENTHAL, CONNECTICUT BOGER MARSHALL, KANSAS

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United States Senate

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS WASHINGTON, DC 20510-6250

April 25, 2023

The Honorable Xavier Becerra Secretary Department of Health and Human Services

Dear Secretary Becerra:

On March 17, 2023, my office emailed the Department of Health and Human Services' (HHS) office of legislative affairs staff and requested unredacted copies of 106 pages of documents that had been recently released to Judicial Watch through a Freedom of Information Act (FOIA) request.¹ To date, HHS has failed to provide these documents and so I am sending a formal letter requesting the immediate production of the unredacted records.

The heavily redacted FOIA documents contain a February 26, 2021 email from Dr. Tess Lawrie to HHS and Food and Drug Administration (FDA) officials apparently sharing information from the British Ivermectin Recommendation Development (BIRD) organization that concluded that "ivermectin should be approved immediately for the prevention and treatment of covid-19."² That email appears to contain an attachment of 104 pages, which are entirely redacted except for the phrase "BIRD Working draft version 1.3," appearing at the top of several pages.³ According to the FOIA documents, shortly after then-Acting FDA Commissioner Janet Woodcock received Dr. Lawrie's email and attachment, she forwarded the message to other public health officials including Francis Collins, then-director of the National Institutes of Health, and Anthony Fauci, then-director of the National Institute of Allergy and Infectious Diseases (NIAID).⁴ It appears that in addition to forwarding Dr. Lawrie's email, Dr. Woodcock also wrote her own message to Drs. Collins, Fauci, and others, however, that message is completely redacted:5

From:	<u>Woodcock, Janet</u>
To:	Kessler, David (HHS/IOS); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; <u>Bugin, Kevin</u>
Subject:	(FDA/CDER); Tevhen, Devdre (HHS/IOS); Adam, Stacev (FNIH) [T] FW: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment
Date:	Friday, February 26, 2021 1:20:25 PM
Attachments:	Draft BIRD Proceedings 25-02-2021 v 1.4.pdf
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¹ Documents produced to Judicial Watch from Health and Human Services, available here: https://www.judicialwatch.org/wpcontent/uploads/2023/03/JW-v-HHS-Collins-Comms-Prod-5-pgs-151-256-02302.pdf.

² Email from Tess Lawrie, Evidence-based Medicine Consultancy, to Janet Woodcock, Acting Commissioner, Food and Drug Administration, et al., Feb. 26, 2021, 10:59 AM, https://www.judicialwatch.org/wp-content/uploads/2023/03/JW-v-HHS-Collins-Comms-Prod-5-pgs-151-256-02302.pdf at 1.

³ Documents produced to Judicial Watch from Health and Human Services, available here: https://www.judicialwatch.org/wpcontent/uploads/2023/03/JW-v-HHS-Collins-Comms-Prod-5-pgs-151-256-02302.pdf at 3-106.

⁴ Email from Janet Woodcock, Acting Commissioner, Food and Drug Administration, to Anthony Fauci, Dir., National Institute of Allergy and Infectious Diseases, et al., Feb. 26, 2021, 1:20 PM, https://www.judicialwatch.org/wpcontent/uploads/2023/03/JW-v-HHS-Collins-Comms-Prod-5-pgs-151-256-02302.pdf at 1.

⁵ Id.

The Honorable Xavier Becerra April 25, 2023 Page 2

The public has a right to know what information HHS, FDA, NIH, and NIAID officials reviewed regarding the effectiveness of ivermectin and how it considered or dismissed certain data. It's past time for HHS to lift the redactions on the enclosed 106 pages and be transparent with the American people.

Please provide unredacted copies of the enclosed documents as soon as possible but no later than May 2, 2023. Thank you for your attention to this matter.

Sincerely,

Ron Johnson

Ron Johnson Ranking Member Permanent Subcommittee on Investigations

Enclosure

cc: The Honorable Richard Blumenthal Chairman Permanent Subcommittee on Investigations

> The Honorable Christi Grimm Inspector General Department of Health and Human Services

Enclosure

From:	Woodcock, Janet
То:	Kessler, David (HHS/IOS); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Bugin, Kevin
	(FDA/CDER); Teyhen, Deydre (HHS/IOS); Adam, Stacey (FNIH) [T]
Subject:	FW: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment
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Attachments:	Draft BIRD Proceedings 25-02-2021 v 1.4.pdf

^{(b) (5)}. jw

From: Tess Lawrie <tess@e-bmc.co.uk>

Sent: Friday, February 26, 2021 10:59 AM

To: Abernethy, Amy < Amy. Abernethy@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; james.sigg@fda.hhs.gov; Tyler, James <James.Tyler@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; Miller, Elizabeth <Elizabeth.Miller@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Pazdur, Richard <Richard.Pazdur@fda.hhs.gov>; Jeffrey.shuren@fda.hhs.gov; Slikker, William <William.Slikker@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Mitch.zeller@fda.hhs.gov; Stein, Peter <Peter.Stein@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Sally.chloe@fda.hhs.gov **Cc:** claire Mock-Muñoz de Luna <claire@e-bmc.co.uk>; Ketan Gajjar <ketan.gajjar@nhs.net>; Andy (b) (6); Scott Mitchell Bryant <andy.bryant@newcastle.ac.uk>; Tony Tham <scott.mitchell@gov.gg>; Tina Peers <tina@drtinapeers.com>

Subject: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Stein and FDA Colleagues,

We are writing to share with you the evidence to decision framework of the British Ivermectin Recommendation Development (BIRD) Meeting that was held on Saturday 20th February 2021 via Zoom from Bath, United Kingdom. The expert panel of health and allied professionals and other stakeholders included representatives from 16 countries, namely Argentina, Australia, Belgium, Botswana, Canada, France, Hungary, India, Ireland, Japan, Peru, Nigeria, South Africa, The Philippines, United States, United Kingdom. The ethos of the BIRD meeting was that of scientific rigour and transparency in the spirit of international collaboration towards a common goal – that of saving lives.

The recommendation was developed according *The WHO Handbook of Guideline Development (2014)*. BIRD panel conclusions are that ivermectin should be approved immediately for prevention and treatment of covid-19.

The BIRD recommendation on covid-19 prevention and treatment

The British Ivermectin Recommendation Development Panel recommends ivermectin for the prevention and treatment of covid-19 to reduce morbidity and mortality associated with covid-19 infection and to prevent covid-19 infection among those at higher risk.

The BIRD Steering Group has taken heed of the WHO statement on 'Developing global norms for sharing data and results during public health emergencies' that states that 'public disclosure of information of relevance to public health emergencies should not be delayed', and also notes the' very great risks' that can occur from 'withholding data and results arising from analyses'. We are, therefore, sharing this evidence-to decision framework within just a few days of the BIRD meeting to avoid delay.

Further, due to the urgency related to the communication and dissemination of this recommendation that is aimed at saving thousands of lives daily, please forgive the limitations of the draft proceedings document attached. Information on the process and methods can be found among the annexes. An Executive Summary is being finalised and will be available on Monday.

We look forward to hearing from you soon and would be happy meet with you via teleconference if you think this will be helpful.

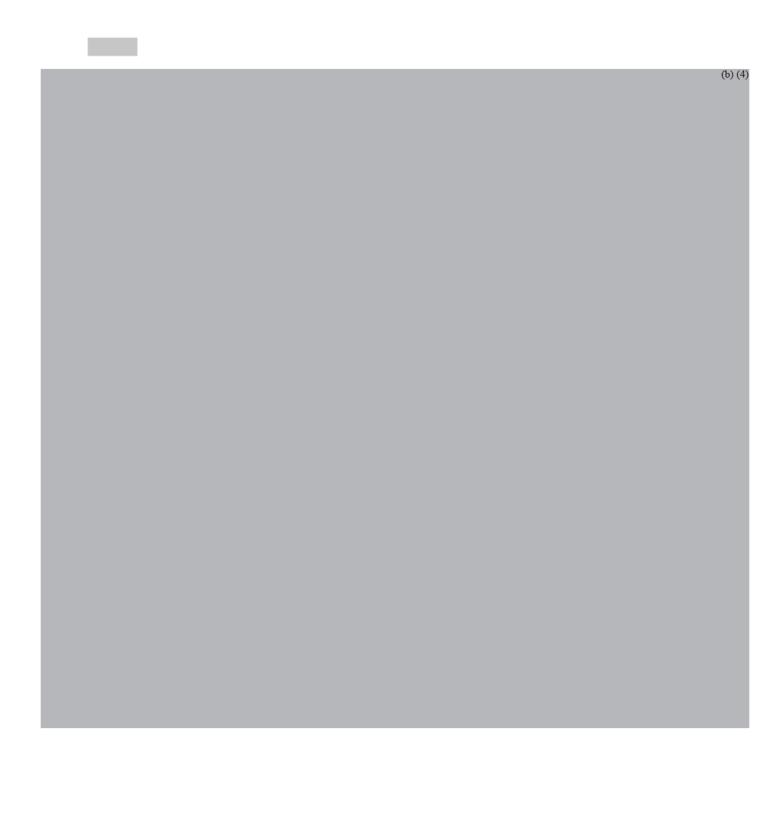
Please do not hesitate to contact us with any questions.

Kind regards,

Dr. Tess Lawrie, on behalf of the BIRD Steering Group and Recommendation Development Panel Evidence-based Medicine Consultancy Ltd <u>e-bmc.co.uk</u>

Obtained via FOIA by Judicial Watch, Inc.

Obtained via FOIA by Judicial Watch, Inc.



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BIRD Working draft version 1.3

BIRD Working draft version 1.3

BIRD Working draft version 1.3

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