



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 8, 2021

Austin Evers
American Oversight
1030 15th Street NW
Suite B255
Washington, District of Columbia 20005
Via email:

Dear Mr. Evers:

This letter is regarding to your original attached Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of April 17, 2020, assigned #20-01262-FOIA. You subsequently narrowed the request per your attached April 30, 2020 email and your attached September 11, 2020 email.

We located 140 pages of responsive records (140 pages released in full or part; no pages withheld in full). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption 6.

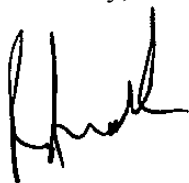
Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as personal email domains. We have determined that the individual(s) to whom this information pertains has a substantial privacy interest in withholding it.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal."

Your appeal must be postmarked or electronically transmitted by July 7, 2021.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Andoh', with a stylized, cursive script.

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

Enclosures

20-01262-FOIA

From: Hein, Alexandria
Sent: Tue, 17 Mar 2020 17:57:19 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Cc: Farber, Madeline
Subject: FoxNews.com Live Blog Opportunity

Hi Dr. Messonnier,

We are running a live-blog on FoxNews.com from 12-1p ET each day featuring a Q&A with an expert. Our readers have been sending in thousands of questions and we've been weeding through them. Would you be interested in participating in the live blog one day next week?

There are two formats we could use – we could email the questions to you ahead of time and you can email us the answers back OR you can answer them in real time while on the phone with Madeline Farber who can type out the answers between 12-1p ET.

Please let us know if you are interested, and if there is a particular date that would work better for you.

Alexandria Hein
Health News Editor
FoxNews.com
212-901-4621

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From: Dr Mehmet Oz
Sent: Sun, 22 Mar 2020 14:25:39 +0000
To: Deborah Leah Birx
Cc: McGuffee, Tyler A. EOP/OVP; Michael Crupain; Redfield, Robert R. (CDC/OD)
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

Thanks for sharing but this does not address the shortage issue. We already have an IRB for prophylaxis and applying for treatment trial today but don't have drugs to complete so please share expectations that can inform our work. Can we at least get batches of drugs for a hundred trial patients? If you don't wish to put in writing, please call but I need guidance for my show and dozens of media interviews that I am doing tomorrow.

Also, the below summary correctly shares that no outcomes data is available from Marseille, but you should know that the French researcher confirmed clinical benefits but needs more data so will not release report for another 10 days. These findings offer hope to our people.

On Mar 22, 2020, at 10:17 AM, Birx, Deborah L. EOP/NSC

(b)(6)

wrote:

Dr Oz

This was posted yesterday on the CDC website and serves to address the issues you raised. Deb

Information for Clinicians on Therapeutic Options for COVID-19 Patients

There are no US Food and Drug Administration (FDA)-approved drugs specifically for the treatment of patients with COVID-19. At present clinical management includes infection prevention and control measures and supportive care, including supplementary oxygen and mechanical ventilatory support when indicated. An array of drugs approved for other indications as well as several investigational drugs are being studied in several hundred clinical trials that are underway across the globe. The purpose of this document is to provide information on two of the approved drugs (chloroquine and hydroxychloroquine) and one of the investigational agents (remdesivir) currently in use in the United States.

Remdesivir

Remdesivir is an investigational intravenous drug with broad antiviral activity that inhibits viral replication through premature termination of RNA transcription and has in-vitro activity against SARS-CoV-2 and in-vitro and in-vivo activity against related betacoronaviruses ^[1-3].

There are currently four options for obtaining remdesivir for treatment of hospitalized patients with COVID-19 and pneumonia in the United States:

- A National Institutes of Health (NIH)-sponsored adaptive double-blinded, placebo-controlled trial of remdesivir versus placebo in COVID-19 patients with pneumonia and hypoxia is enrolling non-pregnant persons aged 18 years and older with oxygen saturation of $\leq 94\%$ on room air or requiring supplemental oxygen or mechanical ventilation (<https://clinicaltrials.gov/ct2/show/NCT04280705>^{external icon}). Exclusion criteria include alanine aminotransaminase or aspartate aminotransaminase levels >5 times the upper limit of normal, stage 4 severe chronic kidney disease or a requirement for dialysis (i.e., estimated glomerular filtration rate (eGFR) <30);
- Two phase 3 randomized open-label trials of remdesivir (5-days versus 10-days versus standard of care) are open to enrollment in persons aged 18 years and older with COVID-19, radiographic evidence of pneumonia and oxygen saturation of $\leq 94\%$ on room air (severe disease <https://clinicaltrials.gov/ct2/show/NCT04292899>^{external icon}) or $>94\%$ on room air (moderate disease <https://clinicaltrials.gov/ct2/show/NCT04292730>^{external icon}). Exclusion criteria include alanine aminotransaminase or aspartate aminotransaminase levels >5 times the upper limit of normal, participation in another clinical trial of an experimental treatment for COVID-19, requirement for mechanical ventilation, or creatinine clearance <50 mL/min; and
- Finally, in areas without clinical trials, COVID-19 patients in the United States and other countries have been treated with remdesivir on an uncontrolled compassionate use basis. While clinical trials are critical to establish the safety and efficacy of this drug, clinicians without access to a clinical trial may request remdesivir for compassionate use through the manufacturer for patients with clinical pneumonia: compassionateaccess@gilead.com

Hydroxychloroquine and Chloroquine

Hydroxychloroquine and chloroquine are oral prescription drugs that have been used for treatment of malaria and certain inflammatory conditions. Chloroquine has been used for malaria treatment and chemoprophylaxis, and hydroxychloroquine is used for treatment of rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. Both drugs have in-vitro activity against SARS-CoV, SARS-CoV-2, and other coronaviruses, with hydroxychloroquine having relatively higher potency against SARS-CoV-2 [14,5]. A study in China reported that chloroquine treatment of COVID-19 patients had clinical and virologic benefit versus a comparison group, and chloroquine was added as a recommended antiviral for treatment of COVID-

19 in China ^[6]. Based upon limited in-vitro and anecdotal data, chloroquine or hydroxychloroquine are currently recommended for treatment of hospitalized COVID-19 patients in several countries. Both chloroquine and hydroxychloroquine have known safety profiles with the main concerns being cardiotoxicity (prolonged QT syndrome) with prolonged use in patients with hepatic or renal dysfunction and immunosuppression but have been reportedly well-tolerated in COVID-19 patients.

Due to higher in-vitro activity against SARS-CoV-2 and its wider availability in the United States compared with chloroquine, hydroxychloroquine has been administered to hospitalized COVID-19 patients on an uncontrolled basis in multiple countries, including in the United States. One small study reported that hydroxychloroquine alone or in combination with azithromycin reduced detection of SARS-CoV-2 RNA in upper respiratory tract specimens compared with a non-randomized control group but did not assess clinical benefit ^[7]. Hydroxychloroquine and azithromycin are associated with QT prolongation and caution is advised when considering these drugs in patients with chronic medical conditions (e.g. renal failure, hepatic disease) or who are receiving medications that might interact to cause arrhythmias.

Hydroxychloroquine is currently under investigation in clinical trials for pre-exposure or post-exposure prophylaxis of SARS-CoV-2 infection, and treatment of patients with mild, moderate, and severe COVID-19. In the United States, several clinical trials of hydroxychloroquine for prophylaxis or treatment of SARS-CoV-2 infection are planned or will be enrolling soon.

More information on trials can be found at: <https://clinicaltrials.gov/external/icon>.

There are no currently available data from Randomized Clinical Trials (RCTs) to inform clinical guidance on the use, dosing, or duration of hydroxychloroquine for prophylaxis or treatment of SARS-CoV-2 infection. Although optimal dosing and duration of hydroxychloroquine for treatment of COVID-19 are unknown, some U.S. clinicians have reported anecdotally different hydroxychloroquine dosing such as: 400mg BID on day one, then daily for 5 days; 400 mg BID on day one, then 200mg BID for 4 days; 600 mg BID on day one, then 400mg daily on days 2-5.

Other Drugs

Lopinavir-ritonavir did not show promise for treatment of hospitalized COVID-19 patients with pneumonia in a recent clinical trial in China ^[8]. This trial was underpowered, and lopinavir-ritonavir is under investigation in a World Health Organization study.

Several other drugs are under investigation in clinical trials or are being considered for clinical trials of prophylaxis or treatment of COVID-19 in the United States and worldwide. Information on registered clinical trials for

COVID-19 in the United States is available at: <https://clinicaltrials.gov/external/icon>.

References

1. Wang M, Cao R, Zhang L, Yang X, Liu J, Xu M, Shi Z, Hu Z, Zhong W, Xiao G. Remdesivir and chloroquine effectively inhibit the recently emerged novel coronavirus (2019-nCoV) in vitro. *Cell Res*. 2020 Mar;30(3):269-271.
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4. Colson P, Rolain JM, Lagier JC, Brouqui P, Raoult D. Chloroquine and hydroxychloroquine as available weapons to fight COVID-19. *Int J Antimicrob Agents*. 2020 Mar 4:105932. doi: 10.1016/j.ijantimicag.2020.105932. [Epub ahead of print]
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Trial of Lopinavir-Ritonavir in Adults Hospitalized with Severe Covid-19. N Engl J Med. 2020 Mar 18. doi: 10.1056/NEJMoa2001282. [Epub ahead of print]

Page last reviewed: March 21, 2020

Content source: [National Center for Immunization and Respiratory Diseases \(NCIRD\)](#), [Division of Viral Diseases](#)

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From: Dr Mehmet Oz <drmoz@zoco.com>
Date: Sunday, March 22, 2020 at 10:11 AM
To: "Birx, Deborah L. EOP/NSC" <(b)(6)>
Cc: "McGuffee, Tyler A. EOP/OVP" <(b)(6)> Michael Crupain <MCrupain@zoco.com>
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

Can we get Taskforce commitment for academic centers to procure at least enough drugs for 100 patient trials like the project below. Does the Taskforce have an idea of the magnitude of shortage and estimates of length of time required to remedy situation?

If we cannot do trials, can we free US clinicians to start using this combo drug protocol. We cannot hide behind study protocols if we are not allowed to proceed. We should have started enrollment on Friday and I want to push brave Americans to join trials on my show tomorrow, but cannot without a game plan for accessing drugs.

P.S. The French physician Raoult argued that withholding access is unethical.

On Mar 22, 2020, at 9:59 AM, Birx, Deborah L. EOP/NSC
<(b)(6)> wrote:

Guidelines to clinicians is coming out today or tomorrow around this essential issue. Deb

From: Dr Mehmet Oz <drmoz@zoco.com>
Date: Sunday, March 22, 2020 at 9:52 AM
To: "Birx, Deborah L. EOP/NSC" <(b)(6)>
Cc: "McGuffee, Tyler A. EOP/OVP" <(b)(6)>, Michael Crupain <MCrupain@zoco.com>
Subject: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

I interviewed the respected Marseille Prof Dr Didier Raoult at 6am today. He authored the French hydroxychloroquine + azithromycin study and has very provocative un-published findings that are worth sharing. I shared his beliefs with my New York Presbyterian – Columbia team and

we are writing IRBs for approval early this week but we need medications. However, in our massive hospital, we currently have enough hydroxychloroquine for 75 patients and azithromycin for 20 patients. I will personally fund the trial and committed \$250,00 but nothing can progress without medications. The President should sequester these medications for clinical trials like ours. Can you help us? I am taping material for tomorrow and would appreciate any advice on how to phrase the Task Force's efforts. Mehmet Oz (b)(6)

From: Birx, Deborah L. EOP/NSC
Sent: Sun, 22 Mar 2020 14:27:03 +0000
To: Dr Mehmet Oz
Cc: McGuffee, Tyler A. EOP/OVP; Michael Crupain; Redfield, Robert R. (CDC/OD)
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Where is the site?

Sent from my iPhone

On Mar 22, 2020, at 10:25 AM, Dr Mehmet Oz <drmoz@zoco.com> wrote:

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References

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From: Dr Mehmet Oz <drmoz@zoco.com>

Date: Sunday, March 22, 2020 at 10:11 AM

To: "Birx, Deborah L. EOP/NSC" <(b)(6)>

Cc: "McGuffee, Tyler A. EOP/OVP" <(b)(6)>

Michael Crupain <MCrupain@zoco.com>

Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

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I interviewed the respected Marseille Prof Dr Didier Raoult at 6am today. He authored the French hydroxychloroquine + azithromycin study and has very provocative un-published findings that are worth sharing. I shared his beliefs with my New York Presbyterian – Columbia team and we are writing IRBs

for approval early this week but we need medications. However, in our massive hospital, we currently have enough hydroxychloroquine for 75 patients and azithromycin for 20 patients. I will personally fund the trial and committed \$250,00 but nothing can progress without medications. The President should sequester these medications for clinical trials like ours. Can you help us? I am taping material for tomorrow and would appreciate any advice on how to phrase the Task Force's efforts.

Mehmet Oz

(b)(6)

From: Dr Mehmet Oz
Sent: Sun, 22 Mar 2020 14:30:02 +0000
To: Deborah Leah Birx
Cc: McGuffee, Tyler A. EOP/OVP; Michael Crupain; Redfield, Robert R. (CDC/OD)
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

New York Presbyterian Hospital (Hospital for Columbia and Cornell) and largest in our region. Famous virus hunter Ian Lipkin (close to Dr Fauci) is leading effort and head of IRB has been great support. I will personally recruit patients and pay for trial. We have manpower since elective surgery is cancelled. We just need drugs.

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Information for Clinicians on Therapeutic Options for COVID-19 Patients

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Remdesivir

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There are currently four options for obtaining remdesivir for treatment of hospitalized patients with COVID-19 and pneumonia in the United States:

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- dialysis (i.e., estimated glomerular filtration rate (eGFR) <30);
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 - Finally, in areas without clinical trials, COVID-19 patients in the United States and other countries have been treated with remdesivir on an uncontrolled compassionate use basis. While clinical trials are critical to establish the safety and efficacy of this drug, clinicians without access to a clinical trial may request remdesivir for compassionate use through the manufacturer for patients with clinical pneumonia: compassionateaccess@gilead.com

Hydroxychloroquine and Chloroquine

Hydroxychloroquine and chloroquine are oral prescription drugs that have been used for treatment of malaria and certain inflammatory conditions.

Chloroquine has been used for malaria treatment and chemoprophylaxis, and hydroxychloroquine is used for treatment of rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. Both drugs have in-vitro activity against SARS-CoV, SARS-CoV-2, and other coronaviruses, with hydroxychloroquine having relatively higher potency against SARS-CoV-2 ^[1,4,5]. A study in China reported that chloroquine treatment of COVID-19 patients had clinical and

virologic benefit versus a comparison group, and chloroquine was added as a recommended antiviral for treatment of COVID-19 in China ^[6]. Based upon limited in-vitro and anecdotal data, chloroquine or hydroxychloroquine are currently recommended for treatment of hospitalized COVID-19 patients in several countries. Both chloroquine and hydroxychloroquine have known safety profiles with the main concerns being cardiotoxicity (prolonged QT syndrome) with prolonged use in patients with hepatic or renal dysfunction and immunosuppression but have been reportedly well-tolerated in COVID-19 patients. Due to higher in-vitro activity against SARS-CoV-2 and its wider availability in the United States compared with chloroquine, hydroxychloroquine has been administered to hospitalized COVID-19 patients on an uncontrolled basis in multiple countries, including in the United States. One small study reported that hydroxychloroquine alone or in combination with azithromycin reduced detection of SARS-CoV-2 RNA in upper respiratory tract specimens compared with a non-randomized control group but did not assess clinical benefit ^[7]. Hydroxychloroquine and azithromycin are associated with QT prolongation and caution is advised when considering these drugs in patients with chronic medical conditions (e.g. renal failure, hepatic disease) or who are receiving medications that might interact to cause arrhythmias. Hydroxychloroquine is currently under investigation in clinical trials for pre-exposure or post-exposure prophylaxis of SARS-CoV-2 infection, and treatment of patients with mild, moderate, and severe COVID-19. In the United States, several clinical trials of hydroxychloroquine for prophylaxis or treatment of SARS-CoV-2 infection are planned or will be enrolling soon. More information on trials can be found at: <https://clinicaltrials.gov/> ^{<external icon>}. There are no currently available data from Randomized Clinical Trials (RCTs) to inform clinical guidance on the use, dosing, or duration of hydroxychloroquine for prophylaxis or treatment of SARS-CoV-2 infection. Although optimal dosing and

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Other Drugs

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, Michael

Crupain <MCrupain@zoco.com>

Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

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P.S. The French physician Raoult argued that withholding access is unethical.

On Mar 22, 2020, at 9:59 AM, Birx,
Deborah L. EOP/NSC

(b)(6)

wrote:

Guidelines to clinicians is coming out today or tomorrow around this essential issue. Deb

From: Dr Mehmet Oz

<drmoz@zoco.com>

Date: Sunday, March 22, 2020 at 9:52 AM

To: "Birx, Deborah L. EOP/NSC"

(b)(6)

Cc: "McGuffee, Tyler A. EOP/OVP"

(b)(6)

v>, Michael Crupain

<MCrupain@zoco.com>

Subject: [EXTERNAL] Urgent Oz:
Clinical Trial Drug Shortage

I interviewed the
respected Marseille Prof
Dr Didier Raoult at 6am
today. He authored the
French
hydroxychloroquine +
azithromycin study and
has very provocative
un-published findings
that are worth sharing.

I shared his beliefs with
my New York
Presbyterian –
Columbia team and we
are writing IRBs for
approval early this
week but we need
medications.

However, in our
massive hospital, we
currently have enough
hydroxychloroquine for
75 patients and
azithromycin for 20
patients. I will
personally fund the trial
and committed \$250,00
but nothing can

progress without medications. The President should sequester these medications for clinical trials like ours. Can you help us? I am taping material for tomorrow and would appreciate any advice on how to phrase the Task Force's efforts.

Mehmet Oz

(b)(6)

(b)(6)

From: Dr Mehmet Oz
Sent: Sun, 22 Mar 2020 14:44:37 +0000
To: Deborah Leah Birx
Cc: McGuffee, Tyler A. EOP/OVP;Michael Crupain;Redfield, Robert R. (CDC/OD)
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

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(b)(6)

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Sent from my iPhone

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New York Presbyterian Hospital (Hospital for Columbia and Cornell) and largest in our region. Famous virus hunter Ian Lipkin (close to Dr Fauci) is leading effort and head of IRB has been great support. I will personally recruit patients and pay for trial. We have manpower since elective surgery is cancelled. We just need drugs.

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This was posted yesterday on the CDC website and serves to address the issues you raised. Deb

Information for Clinicians on Therapeutic Options for COVID-19 Patients

There are no US Food and Drug Administration (FDA)-approved drugs specifically for the treatment of patients with COVID-19. At present clinical management includes infection prevention and control

measures and supportive care, including supplementary oxygen and mechanical ventilatory support when indicated. An array of drugs approved for other indications as well as several investigational drugs are being studied in several hundred clinical trials that are underway across the globe. The purpose of this document is to provide information on two of the approved drugs (chloroquine and hydroxychloroquine) and one of the investigational agents (remdesivir) currently in use in the United States.

Remdesivir

Remdesivir is an investigational intravenous drug with broad antiviral activity that inhibits viral replication through premature termination of RNA transcription and has in-vitro activity against SARS-CoV-2 and in-vitro and in-vivo activity against related betacoronaviruses ^[1-3].

There are currently four options for obtaining remdesivir for treatment of hospitalized patients with COVID-19 and pneumonia in the United States:

- A National Institutes of Health (NIH)-sponsored adaptive double-blinded, placebo-controlled trial of remdesivir versus placebo in COVID-19 patients with pneumonia and hypoxia is enrolling non-pregnant

persons aged 18 years and older with oxygen saturation of $\leq 94\%$ on room air or requiring supplemental oxygen or mechanical ventilation

(<https://clinicaltrials.gov/ct2/show/NCT04280705>; external icon). Exclusion criteria include alanine aminotransaminase or aspartate aminotransaminase levels >5 times the upper limit of normal, stage 4 severe chronic kidney disease or a requirement for dialysis (i.e., estimated glomerular filtration rate (eGFR) <30);

- Two phase 3 randomized open-label trials of remdesivir (5-days versus 10-days versus standard of care) are open to enrollment in persons aged 18 years and older with COVID-19, radiographic evidence of pneumonia and oxygen saturation of $\leq 94\%$ on room air (severe disease <https://clinicaltrials.gov/ct2/show/NCT04292899>; external icon) or $>94\%$ on room air (moderate disease <https://clinicaltrials.gov/ct2/show/NCT04292730>; external icon). Exclusion criteria include alanine aminotransaminase or aspartate aminotransaminase levels >5 times the upper limit of normal, participation in

another clinical trial of an experimental treatment for COVID-19, requirement for mechanical ventilation, or creatinine clearance <50 mL/min; and

- Finally, in areas without clinical trials, COVID-19 patients in the United States and other countries have been treated with remdesivir on an uncontrolled compassionate use basis. While clinical trials are critical to establish the safety and efficacy of this drug, clinicians without access to a clinical trial may request remdesivir for compassionate use through the manufacturer for patients with clinical pneumonia: compassionateaccess@gilead.com

Hydroxychloroquine and Chloroquine

Hydroxychloroquine and chloroquine are oral prescription drugs that have been used for treatment of malaria and certain inflammatory conditions. Chloroquine has been used for malaria treatment and chemoprophylaxis, and hydroxychloroquine is used for treatment of rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. Both drugs have in-vitro activity against SARS-CoV, SARS-CoV-2, and other coronaviruses, with

hydroxychloroquine having relatively higher potency against SARS-CoV-2 [13,3]. A study in China reported that chloroquine treatment of COVID-19 patients had clinical and virologic benefit versus a comparison group, and chloroquine was added as a recommended antiviral for treatment of COVID-19 in China [6]. Based upon limited in-vitro and anecdotal data, chloroquine or hydroxychloroquine are currently recommended for treatment of hospitalized COVID-19 patients in several countries. Both chloroquine and hydroxychloroquine have known safety profiles with the main concerns being cardiotoxicity (prolonged QT syndrome) with prolonged use in patients with hepatic or renal dysfunction and immunosuppression but have been reportedly well-tolerated in COVID-19 patients. Due to higher in-vitro activity against SARS-CoV-2 and its wider availability in the United States compared with chloroquine, hydroxychloroquine has been administered to hospitalized COVID-19 patients on an uncontrolled basis in multiple countries, including in the United States. One small study reported that hydroxychloroquine alone or in combination with azithromycin

reduced detection of SARS-CoV-2 RNA in upper respiratory tract specimens compared with a non-randomized control group but did not assess clinical benefit [2]. Hydroxychloroquine and azithromycin are associated with QT prolongation and caution is advised when considering these drugs in patients with chronic medical conditions (e.g. renal failure, hepatic disease) or who are receiving medications that might interact to cause arrhythmias.

Hydroxychloroquine is currently under investigation in clinical trials for pre-exposure or post-exposure prophylaxis of SARS-CoV-2 infection, and treatment of patients with mild, moderate, and severe COVID-19. In the United States, several clinical trials of hydroxychloroquine for prophylaxis or treatment of SARS-CoV-2 infection are planned or will be enrolling soon. More information on trials can be found at:

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[external icon.](#)

There are no currently available data from Randomized Clinical Trials (RCTs) to inform clinical guidance on the use, dosing, or duration of hydroxychloroquine for prophylaxis or treatment of SARS-CoV-2 infection.

Although optimal dosing and duration of hydroxychloroquine

for treatment of COVID-19 are unknown, some U.S. clinicians have reported anecdotally different hydroxychloroquine dosing such as: 400mg BID on day one, then daily for 5 days; 400 mg BID on day one, then 200mg BID for 4 days; 600 mg BID on day one, then 400mg daily on days 2-5.

Other Drugs

Lopinavir-ritonavir did not show promise for treatment of hospitalized COVID-19 patients with pneumonia in a recent clinical trial in China [8]. This trial was underpowered, and lopinavir-ritonavir is under investigation in a World Health Organization study.

Several other drugs are under investigation in clinical trials or are being considered for clinical trials of prophylaxis or treatment of COVID-19 in the United States and worldwide. Information on registered clinical trials for COVID-19 in the United States is available at: <https://clinicaltrials.gov/> <external icon>.

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Page last reviewed: March 21, 2020

Content source: [National Center for Immunization and Respiratory Diseases \(NCIRD\), Division of Viral Diseases](#)

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- [Are You at Higher Risk for Severe Illness?](#)plus icon
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To receive email updates about COVID-19, enter your email address:

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From: Dr Mehmet Oz

<drmoz@zoco.com>

Date: Sunday, March 22, 2020 at 10:11 AM

To: "Birx, Deborah L. EOP/NSC"

(b)(6)

Cc: "McGuffee, Tyler A. EOP/OVP"

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Michael Crupain
<[MCrupain@zoco.co](mailto:MCrupain@zoco.com)
[m](mailto:MCrupain@zoco.com)>

Subject: [EXTERNAL]
Urgent Oz: Clinical
Trial Drug Shortage

I interviewed
the respected
Marseille Prof
Dr Didier
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today. He

authored the French hydroxychloroquine + azithromycin study and has very provocative unpublished findings that are worth sharing. I shared his beliefs with my New York Presbyterian – Columbia team and we are writing IRBs for approval early this week but we need medications. However, in our massive hospital, we currently have enough hydroxychloroquine for 75 patients and azithromycin for 20 patients. I will

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The President
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To: Dr Mehmet Oz
Cc: McGuffee, Tyler A. EOP/OVP; Michael Crupain; Redfield, Robert R. (CDC/OD)
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Working on getting this information. I know there is available of both drugs in USA. Mylan (hydroxychloroquine) and Pfizer (Z-pak) and there are generic ones available also. You would probably be able to get more direct information from them then I can today. Deb

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Page last reviewed: March 21, 2020

Content source: [National Center for Immunization and Respiratory Diseases \(NCIRD\), Division of Viral Diseases](#)

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To receive email updates about
COVID-19, enter your email
address:

Top of Form

Email Address

[What's this?](#)

Submit

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From: Dr Mehmet Oz

[<drmoz@zoco.com>](mailto:drmoz@zoco.com)

Date: Sunday, March 22, 2020 at
10:11 AM

To: "Birx, Deborah L. EOP/NSC"

[\(b\)\(6\)](#)

Cc: "McGuffee, Tyler A. EOP/OVP"

[\(b\)\(6\)](#)

[v>](#), Michael Crupain

[<MCrupain@zoco.com>](mailto:MCrupain@zoco.com)

Subject: Re: [EXTERNAL] Urgent
Oz: Clinical Trial Drug Shortage

Can we get Taskforce commitment
for academic centers to procure at
least enough drugs for 100 patient
trials like the project below. Does
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P.S. The French physician Raoult argued that withholding access is unethical.

On Mar 22, 2020, at
9:59 AM, Birx, Deborah
L. EOP/NSC

(b)(6)

(b)(6)

wrote:

Guidelines to clinicians
is coming out today or
tomorrow around this
essential issue. Deb

From: Dr Mehmet Oz
<drmoz@zoco.com>
Date: Sunday, March
22, 2020 at 9:52 AM
To: "Birx, Deborah L.
EOP/NSC"

(b)(6)

(b)(6)

Cc: "McGuffee, Tyler
A. EOP/OVP"

(b)(6)

(b)(6)

Michael Crupain

[<MCrupain@zoco.com>](mailto:MCrupain@zoco.com)

Subject: [EXTERNAL]
Urgent Oz: Clinical
Trial Drug Shortage

I interviewed
the respected
Marseille Prof
Dr Didier
Raoult at 6am
today. He
authored the
French
hydroxychloro
quine +
azithromycin
study and has
very
provocative un-
published
findings that
are worth
sharing. I
shared his
beliefs with my
New York
Presbyterian –
Columbia team
and we are
writing IRBs
for approval
early this week
but we need
medications.

However, in our massive hospital, we currently have enough hydroxychloroquine for 75 patients and azithromycin for 20 patients.

I will personally fund the trial and committed \$250,00 but nothing can progress without medications.

The President should sequester these medications for clinical trials like ours. Can you help us? I am taping material for tomorrow and would appreciate any advice on how to phrase the

Task Force's
efforts.

Mehmet Oz

(b)(7)(D)

From: Dr Mehmet Oz
Sent: Sun, 22 Mar 2020 17:16:12 +0000
To: Deborah Leah Birx
Cc: McGuffee, Tyler A. EOP/OVP; Michael Crupain; Redfield, Robert R. (CDC/OD)
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

My show's medical unit did some research, which is outlined below. I suspect you have a similar dashboard. Only the Federal Government can accelerate the supply chain. How can I help besides replicating the French study?

American Society of Health Systems Pharmacists (ASHP) says there is a

shortage: <https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=646>

The Wapo article that Akshay sent says:

Data gathered in the first 17 days of March by Premier Inc., a large group purchasing organization for 4,000 U.S. hospitals, showed a 300 percent week-over-week increase in orders of chloroquine and a 70 percent week-over-week boost in orders of hydroxychloroquine.

"Both drugs are pretty much depleted right now in the distribution channel and wholesale distributors are reporting both products on back order," said Soumi Saha, senior director of advocacy at Premier.

Companies are reacting to increase supply:

Mylan, which expects to begin supplying the product by mid-April, and with the active pharmaceutical ingredient that it currently has available, will be able to ramp up manufacturing to provide 50 million tablets to potentially treat a total of more than 1.5 million patients. It is also taking steps to initiate production outside the USA in the coming weeks.

Amneal is ramping up production of hydroxychloroquine sulfate at several of its manufacturing sites and expects to produce approximately 20 million tablets between now (MARCH 20) and mid-April. Those tablets will be made available nationwide through Amneal's existing retail and wholesale customers, as well as through direct sales to larger institutions in need.

Novartis/Sandoz intends to donate up to 130 million 200 mg doses by the end of May, including its current stock of 50 million 200 mg doses. Note these are global numbers

- **Teva** will ship 6 Million tablets through wholesalers to hospitals by March 31, and more than 10 Million within a month.

- No comments from Zydus or Prasco

Bayer has a drug called **Resochin** that is chloroquine phosphate, and it's been reported that they donated 3 million doses to US government

On Mar 22, 2020, at 10:47 AM, Birx, Deborah L. EOP/NSC

(b)(6)

> wrote:

Working on getting this information. I know there is available of both drugs in USA. Mylan (hydroxychloroquine) and Pfizer (Z-pak) and there are generic ones available also. You would probably be able to get more direct information from them then I can today. Deb

From: Dr Mehmet Oz <drmoz@zoco.com>

Date: Sunday, March 22, 2020 at 10:44 AM

To: "Birx, Deborah L. EOP/NSC"

(b)(6)

Cc: "McGuffee, Tyler A. EOP/OVP"

(b)(6)

Michael

Crupain <MCrupain@zoco.com>, "olx1@cdc.gov" <olx1@cdc.gov>

Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

What should I say about the coronavirus drug shortage to America? Should I ask my viewers to return pills? Is the task force re-distributing to hard hit areas? How can I help deliver the right message which is not addressed in the current govt documents anywhere.

On Mar 22, 2020, at 10:31 AM, Birx, Deborah L. EOP/NSC

(b)(6)

wrote:

Thank you. Yes I know Ian. He is an icon in our field. Deb

Sent from my iPhone

On Mar 22, 2020, at 10:30 AM, Dr Mehmet Oz

<drmoz@zoco.com> wrote:

New York Presbyterian Hospital (Hospital for Columbia and Cornell) and largest in our region. Famous virus hunter Ian Lipkin (close to Dr Fauci) is leading effort and head of IRB has been great support. I will personally recruit patients and pay for trial. We have manpower since elective surgery is cancelled. We just need drugs.

On Mar 22, 2020, at 10:27 AM, Birx, Deborah L. EOP/NSC

(b)(6)

wrote:

Where is the site?

Sent from my iPhone

On Mar 22, 2020, at 10:25 AM, Dr Mehmet Oz <drmoz@zoco.com> wrote:

Thanks for sharing but this does not address the shortage issue. We already have an IRB for prophylaxis and applying for treatment trial today but don't have drugs to complete so please share expectations that can inform our work. Can we at least get batches of drugs for a hundred trial patients? If you don't wish to put in writing, please call but I need guidance for my show and dozens of media interviews that I am doing tomorrow.

Also, the below summary correctly shares that no outcomes data is available from Marseille, but you should know that the French researcher confirmed clinical benefits but needs more data so will not release report for another 10 days. These findings offer hope to our people.

On Mar 22, 2020, at 10:17 AM, Bix, Deborah L. EOP/NSC

(b)(6)

(b)(6)

wrote:

Dr Oz

This was posted yesterday on the CDC website and

serves to address
the issues you
raised. Deb

Information for Clinicians on Therapeutic Options for COVID-19 Patients

There are no US
Food and Drug
Administration
(FDA)-approved
drugs specifically
for the treatment of
patients with
COVID-19. At
present clinical
management
includes infection
prevention and
control measures
and supportive care,
including
supplementary
oxygen and
mechanical
ventilatory support
when indicated. An
array of drugs
approved for other
indications as well

as several investigational drugs are being studied in several hundred clinical trials that are underway across the globe. The purpose of this document is to provide information on two of the approved drugs (chloroquine and hydroxychloroquine) and one of the investigational agents (remdesivir) currently in use in the United States.

Remdesivir

Remdesivir is an investigational intravenous drug with broad antiviral activity that inhibits viral replication through premature termination of RNA transcription and has in-vitro activity against SARS-CoV-2 and in-vitro and in-vivo activity against related betacoronaviruses ^[1-3].

There are currently four options for obtaining remdesivir for treatment of hospitalized patients

with COVID-19 and pneumonia in the United States:

- A National Institutes of Health (NIH)-sponsored adaptive double-blinded, placebo-controlled trial of remdesivir versus placebo in COVID-19 patients with pneumonia and hypoxia is enrolling non-pregnant persons aged 18 years and older with oxygen saturation of $\leq 94\%$ on room air or requiring supplemental oxygen or mechanical ventilation (<https://clinicaltrials.gov/ct2/show/NCT04280705>; [external icon](#)). Exclusion criteria include alanine aminotransaminase or aspartate aminotransaminase levels >5 times the upper limit of normal, stage 4 severe chronic kidney disease or a requirement for

dialysis (i.e.,
estimated
glomerular
filtration rate
(eGFR) <30);

- Two phase 3
randomized open-
label trials of
remdesivir (5-
days versus 10-
days versus
standard of care)
are open to
enrollment in
persons aged 18
years and older
with COVID-19,
radiographic
evidence of
pneumonia and
oxygen saturation
of $\leq 94\%$ on room
air (severe
disease >>><https://clinicaltrials.gov/ct2/show/NCT04292899><<<;exter
nal icon) or $>94\%$
on room air
(moderate
disease >>><https://clinicaltrials.gov/ct2/show/NCT04292730><<<;exter
nal icon).
Exclusion criteria
include alanine
aminotransamina
se or aspartate
aminotransamina
se levels >5 times
the upper limit of
normal,

participation in another clinical trial of an experimental treatment for COVID-19, requirement for mechanical ventilation, or creatinine clearance <50 mL/min; and

- Finally, in areas without clinical trials, COVID-19 patients in the United States and other countries have been treated with remdesivir on an uncontrolled compassionate use basis. While clinical trials are critical to establish the safety and efficacy of this drug, clinicians without access to a clinical trial may request remdesivir for compassionate use through the manufacturer for patients with clinical pneumonia: compassionateaccess@gilead.com

Hydroxychloroquine and Chloroquine

Hydroxychloroquine and chloroquine are oral prescription drugs that have been used for treatment of malaria and certain inflammatory conditions.

Chloroquine has been used for malaria treatment and chemoprophylaxis, and

hydroxychloroquine is used for treatment of rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. Both drugs have in-vitro activity against SARS-CoV, SARS-CoV-2, and other coronaviruses, with hydroxychloroquine having relatively higher potency against SARS-CoV-2 [\[1,4,5\]](#).

A study in China reported that chloroquine treatment of COVID-19 patients had clinical and virologic benefit versus a comparison

group, and chloroquine was added as a recommended antiviral for treatment of COVID-19 in China ^[6]. Based upon limited in-vitro and anecdotal data, chloroquine or hydroxychloroquine are currently recommended for treatment of hospitalized COVID-19 patients in several countries. Both chloroquine and hydroxychloroquine have known safety profiles with the main concerns being cardiotoxicity (prolonged QT syndrome) with prolonged use in patients with hepatic or renal dysfunction and immunosuppression but have been reportedly well-tolerated in COVID-19 patients. Due to higher in-vitro activity against SARS-CoV-2 and its wider availability in the United States compared with chloroquine,

hydroxychloroquine has been administered to hospitalized COVID-19 patients on an uncontrolled basis in multiple countries, including in the United States. One small study reported that hydroxychloroquine alone or in combination with azithromycin reduced detection of SARS-CoV-2 RNA in upper respiratory tract specimens compared with a non-randomized control group but did not assess clinical benefit [2]. Hydroxychloroquine and azithromycin are associated with QT prolongation and caution is advised when considering these drugs in patients with chronic medical conditions (e.g. renal failure, hepatic disease) or who are receiving medications that might interact to cause arrhythmias. Hydroxychloroquine is currently under investigation in

clinical trials for
pre-exposure or
post-exposure
prophylaxis of
SARS-CoV-2
infection, and
treatment of patients
with mild,
moderate, and
severe COVID-19.

In the United States,
several clinical trials
of
hydroxychloroquine
for prophylaxis or
treatment of SARS-
CoV-2 infection are
planned or will be
enrolling soon.

More information
on trials can be
found at:

<https://clinicaltrials.gov/ct2/external/icon>

There are no
currently available
data from
Randomized
Clinical Trials
(RCTs) to inform
clinical guidance on
the use, dosing, or
duration of
hydroxychloroquine
for prophylaxis or
treatment of SARS-
CoV-2 infection.

Although optimal
dosing and duration
of
hydroxychloroquine
for treatment of

COVID-19 are unknown, some U.S. clinicians have reported anecdotally different hydroxychloroquine dosing such as: 400mg BID on day one, then daily for 5 days; 400 mg BID on day one, then 200mg BID for 4 days; 600 mg BID on day one, then 400mg daily on days 2-5.

Other Drugs

Lopinavir-ritonavir did not show promise for treatment of hospitalized COVID-19 patients with pneumonia in a recent clinical trial in China [\[8\]](#). This trial was underpowered, and lopinavir-ritonavir is under investigation in a World Health Organization study. Several other drugs are under investigation in clinical trials or are being considered for clinical trials of prophylaxis or treatment of COVID-19 in the United States and

worldwide.
Information on
registered clinical
trials for COVID-19
in the United States
is available
at: >>>[>>>https://clinicaltrials.gov/](https://clinicaltrials.gov/)<<<::external icon.

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Guidance
for
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Options

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email_03Get Email
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To receive email
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Email Address

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Michael Crupain
<MCrupain@zoco.com>

Subject: Re:
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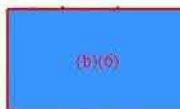
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Michael

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Subject: [EXTERNA
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Mehm
et Oz



From: Birx, Deborah L. EOP/NSC
Sent: Sun, 22 Mar 2020 20:58:20 +0000
To: Dr Mehmet Oz
Cc: McGuffee, Tyler A. EOP/OVP; Michael Crupain; Redfield, Robert R. (CDC/OD); Boehler, Adam
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

Dr Oz
Here you go – keep us updated -

From: Dr Mehmet Oz <drmoz@zoco.com>
Date: Sunday, March 22, 2020 at 4:32 PM
To: "Birx, Deborah L. EOP/NSC" <(b)(6)>
Cc: "McGuffee, Tyler A. EOP/OVP" <(b)(6)>, Michael Crupain <MCrupain@zoco.com>, "olx1@cdc.gov" <olx1@cdc.gov>
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

I found hydroxychloroquine in Washington (of all places) so we are set for our NYC clinical trial. Cleveland Clinic and at least one other center is also moving forward so should have results in a week, although we could start treating earlier as we discussed Friday.

Can you connect me to Adam Boehler to discuss creation of a "Digital Vaccine" with our country's Tech companies when convenient. Take care

On Mar 22, 2020, at 10:47 AM, Birx, Deborah L. EOP/NSC <(b)(6)> wrote:

Working on getting this information. I know there is available of both drugs in USA. Mylan (hydroxychloroquine) and Pfizer (Z-pak) and there are generic ones available also. You would probably be able to get more direct information from them then I can today. Deb

From: Dr Mehmet Oz <drmoz@zoco.com>
Date: Sunday, March 22, 2020 at 10:44 AM
To: "Birx, Deborah L. EOP/NSC" <(b)(6)>
Cc: "McGuffee, Tyler A. EOP/OVP" <(b)(6)>, Michael Crupain <MCrupain@zoco.com>, "olx1@cdc.gov" <olx1@cdc.gov>
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

What should I say about the coronavirus drug shortage to America? Should I ask my viewers to return pills? Is the task force re-distributing to hard hit areas? How can I help deliver the right message which is not addressed in the current govt documents anywhere.

On Mar 22, 2020, at 10:31 AM, Birx, Deborah L. EOP/NSC

(b)(6)

wrote:

Thank you. Yes I know Ian. He is an icon in our field. Deb

Sent from my iPhone

On Mar 22, 2020, at 10:30 AM, Dr Mehmet Oz

<drmoz@zoco.com> wrote:

New York Presbyterian Hospital (Hospital for Columbia and Cornell) and largest in our region. Famous virus hunter Ian Lipkin (close to Dr Fauci) is leading effort and head of IRB has been great support. I will personally recruit patients and pay for trial. We have manpower since elective surgery is cancelled. We just need drugs.

On Mar 22, 2020, at 10:27 AM, Birx, Deborah L.

EOP/NSC (b)(6) wrote:

Where is the site?

Sent from my iPhone

On Mar 22, 2020, at 10:25 AM, Dr

Mehmet Oz <drmoz@zoco.com>

wrote:

Thanks for sharing but this does not address the shortage issue. We already have an IRB for prophylaxis and applying for treatment trial today but don't have drugs to complete so please share expectations that can inform our work. Can we at least get batches of

drugs for a hundred trial patients? If you don't wish to put in writing, please call but I need guidance for my show and dozens of media interviews that I am doing tomorrow.

Also, the below summary correctly shares that no outcomes data is available from Marseille, but you should know that the French researcher confirmed clinical benefits but needs more data so will not release report for another 10 days. These findings offer hope to our people.

On Mar 22, 2020, at
10:17 AM, Birx,
Deborah L. FOP/NSC

(b)(6)

(b)(6)

rote:

Dr Oz

This was posted
yesterday on the
CDC website and
serves to address
the issues you
raised. Deb

Information
for
Clinicians
on
Therapeutic
Options

for COVID-19 Patients

There are no US Food and Drug Administration (FDA)-approved drugs specifically for the treatment of patients with COVID-19. At present clinical management includes infection prevention and control measures and supportive care, including supplementary oxygen and mechanical ventilatory support when indicated. An array of drugs approved for other indications as well as several investigational drugs are being studied in several hundred clinical trials that are underway across the globe. The purpose of this document is to provide information on two of the approved drugs (chloroquine and

hydroxychloroquine
) and one of the
investigational
agents (remdesivir)
currently in use in
the United States.

Remdesivir

Remdesivir is an
investigational
intravenous drug
with broad antiviral
activity that inhibits
viral replication
through premature
termination of RNA
transcription and
has in-vitro activity
against SARS-CoV-
2 and in-vitro and
in-vivo activity
against related
betacoronaviruses [1-
3].

There are currently
four options for
obtaining remdesivir
for treatment of
hospitalized patients
with COVID-19 and
pneumonia in the
United States:

- A National
Institutes of
Health (NIH)-
sponsored
adaptive double-
blinded, placebo-
controlled trial of
remdesivir versus
placebo in
COVID-19
patients with

pneumonia and hypoxia is enrolling non-pregnant persons aged 18 years and older with oxygen saturation of $\leq 94\%$ on room air or requiring supplemental oxygen or mechanical ventilation

(<https://clinicaltrials.gov/ct2/show/NCT04280705>; external icon).

Exclusion criteria include alanine aminotransaminase or aspartate aminotransaminase levels > 5 times the upper limit of normal, stage 4 severe chronic kidney disease or a requirement for dialysis (i.e., estimated glomerular filtration rate (eGFR) < 30);

- Two phase 3 randomized open-label trials of remdesivir (5-days versus 10-days versus standard of care) are open to enrollment in

persons aged 18 years and older with COVID-19, radiographic evidence of pneumonia and oxygen saturation of $\leq 94\%$ on room air (severe disease >>>><https://clinicaltrials.gov/ct2/show/NCT04292899><<<<;; external icon) or $>94\%$ on room air (moderate disease >>>><https://clinicaltrials.gov/ct2/show/NCT04292730><<<<;; external icon).

Exclusion criteria include alanine aminotransaminase or aspartate aminotransaminase levels >5 times the upper limit of normal, participation in another clinical trial of an experimental treatment for COVID-19, requirement for mechanical ventilation, or creatinine clearance <50 mL/min; and

- Finally, in areas without clinical

trials, COVID-19 patients in the United States and other countries have been treated with remdesivir on an uncontrolled compassionate use basis. While clinical trials are critical to establish the safety and efficacy of this drug, clinicians without access to a clinical trial may request remdesivir for compassionate use through the manufacturer for patients with clinical pneumonia: compassionateaccess@gilead.com

Hydroxychloroquine and Chloroquine

Hydroxychloroquine and chloroquine are oral prescription drugs that have been used for treatment of malaria and certain inflammatory conditions. Chloroquine has been used for

malaria treatment and chemoprophylaxis, and hydroxychloroquine is used for treatment of rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. Both drugs have in-vitro activity against SARS-CoV, SARS-CoV-2, and other coronaviruses, with hydroxychloroquine having relatively higher potency against SARS-CoV-2 ^[1,4,5]. A study in China reported that chloroquine treatment of COVID-19 patients had clinical and virologic benefit versus a comparison group, and chloroquine was added as a recommended antiviral for treatment of COVID-19 in China ^[6]. Based upon limited in-vitro and anecdotal data, chloroquine or hydroxychloroquine are currently recommended for treatment of

hospitalized COVID-19 patients in several countries. Both chloroquine and hydroxychloroquine have known safety profiles with the main concerns being cardiotoxicity (prolonged QT syndrome) with prolonged use in patients with hepatic or renal dysfunction and immunosuppression but have been reportedly well-tolerated in COVID-19 patients. Due to higher in-vitro activity against SARS-CoV-2 and its wider availability in the United States compared with chloroquine, hydroxychloroquine has been administered to hospitalized COVID-19 patients on an uncontrolled basis in multiple countries, including in the United States. One small study reported that hydroxychloroquine alone or in combination with azithromycin

reduced detection of SARS-CoV-2 RNA in upper respiratory tract specimens compared with a non-randomized control group but did not assess clinical benefit [4]. Hydroxychloroquine and azithromycin are associated with QT prolongation and caution is advised when considering these drugs in patients with chronic medical conditions (e.g. renal failure, hepatic disease) or who are receiving medications that might interact to cause arrhythmias. Hydroxychloroquine is currently under investigation in clinical trials for pre-exposure or post-exposure prophylaxis of SARS-CoV-2 infection, and treatment of patients with mild, moderate, and severe COVID-19. In the United States, several clinical trials of hydroxychloroquine for prophylaxis or

treatment of SARS-CoV-2 infection are planned or will be enrolling soon.

More information on trials can be found at:

<https://clinicaltrials.gov/ct2/external/icon>.

There are no currently available data from Randomized Clinical Trials (RCTs) to inform clinical guidance on the use, dosing, or duration of hydroxychloroquine for prophylaxis or treatment of SARS-CoV-2 infection.

Although optimal dosing and duration of hydroxychloroquine for treatment of COVID-19 are unknown, some U.S. clinicians have reported anecdotally different

hydroxychloroquine dosing such as: 400mg BID on day one, then daily for 5 days; 400 mg BID on day one, then 200mg BID for 4 days; 600 mg BID on day one, then

400mg daily on
days 2-5.

Other Drugs

Lopinavir-ritonavir
did not show
promise for
treatment of
hospitalized
COVID-19 patients
with pneumonia in a
recent clinical trial
in China [8]. This
trial was
underpowered, and
lopinavir-ritonavir is
under investigation
in a World Health
Organization study.
Several other drugs
are under
investigation in
clinical trials or are
being considered for
clinical trials of
prophylaxis or
treatment of
COVID-19 in the
United States and
worldwide.

Information on
registered clinical
trials for COVID-19
in the United States
is available

at: >>>><https://clinicaltrials.gov/><<<<;
[external icon](#).

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Page last
reviewed: March 21,
2020

Content
source: [National
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Diseases
\(NCIRD\), Division
of Viral Diseases
Coronavirus Disease
2019 \(COVID-19\)](#)

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- [Communication Resourcesplus icon](#)

email_03Get Email Updates
To receive email updates about

COVID-19, enter
your email address:

Top of Form

Email Address

[What's this?](#)

Submit

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From: Dr Mehmet Oz
<drmoz@zoco.com>

Date: Sunday, March
22, 2020 at 10:11 AM

To: "Birx, Deborah L.
EOP/NSC"

(b)(6)

(b)(6)

Cc: "McGuffee, Tyler
A. EOP/OVP"

(b)(6)

(b)(6)

Michael Crupain
<[MCrupain@zoco.co
m](mailto:MCrupain@zoco.com)>

Subject: Re:
[EXTERNAL] Urgent
Oz: Clinical Trial Drug
Shortage

Can we get Taskforce
commitment for
academic centers to
procure at least enough
drugs for 100 patient
trials like the project
below. Does the
Taskforce have an idea
of the magnitude of
shortage and estimates
of length of time
required to remedy
situation?

If we cannot do trials,
can we free US
clinicians to start using
this combo drug
protocol. We cannot
hide behind study
protocols if we are not
allowed to proceed. We
should have started
enrollment on Friday
and I want to push
brave Americans to join
trials on my show
tomorrow, but cannot
without a game plan for
accessing drugs.

P.S. The French
physician Raoult argued
that withholding access
is unethical.

On Mar
22, 2020,
at 9:59
AM, Birx,
Deborah
L.
EOP/NSC

(b)(6)

> wrote:

Guidelines
to
clinicians
is coming
out today
or
tomorrow
around

this
essential
issue.
Deb

From: Dr
Mehmet
Oz
<drmoz@zoco.com>

Date: Sun
day,
March
22, 2020
at 9:52
AM

To: "Birx,
Deborah
L.
EOP/NSC
"

(b)(6)

Cc: "McG
uffee,
Tyler A.
EOP/OVP
"

(b)(6)

Michael
Crupain
<MCrupain@zoco.com>

Subject: [
EXTERNA
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Oz:

Clinical
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medications. However, in our massive hospital, we currently have enough hydroxychloroquine for 75 patients and azithromycin for 20 patients. I will personally fund the trial and

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Mehm
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From: FOIA Requests (CDC) <foiarequests@cdc.gov>
Sent: Thursday, April 30, 2020 1:39 PM EDT
To: Harper, Mark Neville (CDC/OCOO/OD) <wzj6@cdc.gov>
CC: Schofield, LaShonda (CDC/OCOO/OD) <hur7@cdc.gov>
Subject: FW: [Ext]Your CDC FOIA Request #20-01262-FOIA
Attachment(s): "Email Domains for CDC .docx"

FOR YOUR ACTION

Have a*""
,,*,*""*,*"
(,,*(,,* Wonderful Day!

V/R

Carolyn Sanchang-Fon Okpewho
CDC/ATSDR Workstream Leader
Freedom of Information Act Office
Centers for Disease Control and Prevention
Agency for Toxic Substances and Disease Registry
' 770-488-6332 (Direct) | ' 770-488-6399 (Main)
7 404-235-1852 | 8 xxo5@cdc.gov
 Telework ~ Tuesdays & Wednesdays



From: FOIA <foia@americanoversight.org>
Sent: Thursday, April 30, 2020 12:28 PM
To: FOIA Requests (CDC) <foiarequests@cdc.gov>
Subject: Re: [Ext]Your CDC FOIA Request #20-01262-FOIA

Good afternoon Mr. Harper,

We received your letter seeking clarification on our recently filed FOIA request numbered 20-01262-FOIA. In your letter, you stated that the request was not proper because it did not include domain names for the external individuals listed in column B of our request.

As an initial matter, we disagree that a requester is required to provide domain names in order to have reasonably described the communications they are requesting. CDC is capable of searching for communications with individuals or entities even without domain names, using basic search functionality. However, in an effort to be accommodating and to assist with the processing of these requests, we have identified several emails or domain names in the attached word document for CDC to use in an email search. Where we were unable to provide specific emails or domains, we ask that CDC search for the individual's name as described in the attached document.

Please let me know if you have any questions.

Thank you,

Christine

Christine H. Monahan
Counsel
American Oversight
(202) 869-5244
foia@americanoversight.org

From: "Harper, Mark" <foiarequests@cdc.gov>
Date: Wednesday, April 29, 2020 at 11:08 AM
To: FOIA <foia@americanoversight.org>
Subject: [Ext]Your CDC FOIA Request #20-01262-FOIA

April 29, 2020

Request Number: 20-01262-FOIA

Dear Mr. Evers:

This is regarding your Freedom of Information Act (FOIA) request of April 17, 2020, for All communications (including emails, email attachments, text messages, calendar invitations, calendar entries, meeting notices, meeting agendas, or talking points), as well as any summaries of or notes taken during any oral communications, between (a) the government officials listed in Column A below, and (b) the individuals listed in Column B below.[COVID-19].

Please see the attached letter.

Sincerely,
CDC/ATSDR FOIA Office
770-488-6399

Column B: External Individuals	Email / Domain / Alternative Search Term
Larry Ellison	☐ larry.ellison@oracle.com
Dr. Mehmet Oz	☐ Mco2@columbia.edu ☐ Any emails ending in mail.doctoroz.com or zoco.com
Rudy Giuliani, including anyone communicating on his behalf, including but not limited to Jo Ann Zafonte, Christianne Allen, or Beau Wagner	☐ Any emails ending in giulianipartners.com , gdcillc.com , or giulianisecurity.com
Dr. Vladimir Zelenko	☐ "Zelenko"
Ben Shapiro	☐ bshapiro@dailywire.com ☐ bshapiro708@gmail.com
Alex Jones	☐ alex@infowars.com
Gregory Rigano	☐ gregor@iku.network ☐ grigano1@jhu.edu
Dr. Ramin Oskoui	☐ "Oskoui"
Dr. Stephen Smith	☐ Any emails ending in smithcenternj.org
Dr. William Grace	☐ Any emails ending in williamrgracemd.com
Dr. Marc Siegel	☐ marc@doctorsiegel.com ☐ marc.siegel@nyumc.org
Roberto Mignone	☐ "Mignone"
Nitin Saigal	☐ "Saigal"
Chirag Patel	☐ chirag.patel@amneal.com
Ken Fisher	☐ Any emails ending in kenfisher.com or fisherinvestments.com
Bernard Marcus	☐ "Bernie" AND "Marcus" ☐ "Bernard" AND "Marcus"
Dr. Robin Armstrong	☐ "Robin" AND "Armstrong" ☐ "Dr. Armstrong"

From: FOIA Requests (CDC) <foiarequests@cdc.gov>
Sent: Monday, September 14, 2020 7:23 AM EDT
To: Harper, Mark Neville (CDC/OCOO/OD) <wzj6@cdc.gov>
Subject: FW: [Ext]Your CDC FOIA Request #20-01262-FOIA

Good morning Mark,
FYI

Samuel

From: FOIA <foia@americanoversight.org>
Sent: Friday, September 11, 2020 3:15 PM
To: FOIA Requests (CDC) <foiarequests@cdc.gov>
Subject: Re: [Ext]Your CDC FOIA Request #20-01262-FOIA

Hi Mark,

Per our discussion, AO has no objection to dropping the six individuals (Zelenko, Oskoui, Mignone, Saigal, Marcus, and Armstrong) for whom we were unable to provide domains in light of the difficulties that arose just searching for their names.

Thanks for reaching out.

Christine

Christine H. Monahan
Counsel
American Oversight
(202) 869-5244
foia@americanoversight.org

From: Christine Monahan <christine.monahan@americanoversight.org> on behalf of FOIA <foia@americanoversight.org>
Date: Thursday, April 30, 2020 at 12:28 PM
To: "Harper, Mark" <foiarequests@cdc.gov>
Subject: Re: [Ext]Your CDC FOIA Request #20-01262-FOIA

Good afternoon Mr. Harper,

We received your letter seeking clarification on our recently filed FOIA request numbered 20-01262-FOIA. In your letter, you stated that the request was not proper because it did not include domain names for the external individuals listed in column B of our request.

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Please let me know if you have any questions.

Thank you,

Christine

Christine H. Monahan
Counsel
American Oversight
(202) 869-5244
foia@americanoversight.org

From: "Harper, Mark" <foiarequests@cdc.gov>
Date: Wednesday, April 29, 2020 at 11:08 AM
To: FOIA <foia@americanoversight.org>
Subject: [Ext]Your CDC FOIA Request #20-01262-FOIA

April 29, 2020

Request Number: 20-01262-FOIA

Dear Mr. Evers:

This is regarding your Freedom of Information Act (FOIA) request of April 17, 2020, for All communications (including emails, email attachments, text messages, calendar invitations, calendar entries, meeting notices, meeting agendas, or talking points), as well as any summaries of or notes taken during any oral communications, between (a) the government officials listed in Column A below, and (b) the individuals listed in Column B below.[COVID-19].

Please see the attached letter.

Sincerely,
CDC/ATSDR FOIA Office
770-488-6399