

From:	(b)(3):10 USC 424; (b)(6)
To:	
CC:	
Subject:	RE: Hydroxychloroquine and azithromycin drug combination tasker response
Date:	2020/04/01 14:06:54
Priority:	Normal
Type:	Note

Classification: UNCLASSIFIED

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(b)(3):10 USC 424;
(b)(6)

I sent this prematurely, and this needs to be reviewed by OCG and OCC before being published on the FAQ. If it is published, can you please have it deleted. We will submit directly before resending it to (b)(3):10 USC 424; (b)(6) for publishing.

(b)(3):10 USC 424; (b)(6)

(b)(3):10 USC 424; (b)(6)

From: [Redacted]
Sent: Tuesday, March 31, 2020 12:54 PM
To: (b)(3):10 USC 424; (b)(6)
Cc: [Redacted]
Subject: Hydroxychloroquine and azithromycin drug combination tasker response

Classification: UNCLASSIFIED

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Sir,

Please find below the response to the tasker referenced in the subject line for posting in the FAQ. In addition, I was requested to ask for another POC from your office to send materials to for posting to the FAQ in the future.

R,

(b)(3):10 USC 424; (b)(6)

Re: Hydroxychloroquine and azithromycin drug combination tasker response

BLUF: There appears to be a benefit in terms of recovery and blunted viral replication with this combination therapy, but the data are very preliminary and will need to be confirmed in larger randomized clinical trials. It should also be noted that hydroxychloroquine does have some serious side effects that must be considered.

On 28 March, the FDA issued an Emergency Use Authorization (EUA) for both chloroquine and hydroxylchloroquine at the request of Dr. Rick Bright, Director of the Biomedical Advanced Research and Development Authority at the Department of Health and Human Services. The use is limited to a valid clinical indication described in the EUA, a valid prescription from a licensed practitioner, and sourcing from the Strategic National Stockpile.

Limited testing with this combination therapy has resulted in promising but very preliminary results. The individual efforts described below are two small studies showing a positive benefit, a summary of Chinese clinical experience, and a larger planned clinical study to be conducted in Australia.

- One study (<https://www.sciencedirect.com/science/article/pii/S0924857920300996?via%3Dihub>) with a small cohort (34 patients total) concluded that ***"Despite its small sample size our survey shows that hydroxychloroquine treatment is significantly associated with viral load reduction/disappearance in COVID-19 patients and its effect is reinforced by azithromycin."***
- A description of the summary of Chinese clinical evidence (no data shown) makes similar claims (https://www.jstage.jst.go.jp/article/bst/14/1/14_2020/01047/pdf-char/en)
- Another small study showing some benefit from combination therapy (<https://www.medrxiv.org/content/10.1101/2020.03.22.20040949v1.full.pdf>)
- A larger study is being planned in Australia (<https://www.uq.edu.au/news/article/2020/03/researchers-set-begin-clinical-trials-potential-coronavirus-treatment>).

Please let me know if you have any additional questions or if I can be of further help.

R,

(b)(3);10 USC 424; (b)(6)

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Classification: UNCLASSIFIED

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Classification: UNCLASSIFIED

Sender:	(b)(3):10 USC 424; (b)(6)
Recipient:	
Sent Date:	2020/04/01 14:06:52
Delivered Date:	2020/04/01 14:06:54