Information Sheet for Senator Charles E. Schumer
regarding Hydroxychloroquine Use to
Treat Department of Veterans Affairs (VA)
COVID-19 Patients

Question 1: What was the explicit purpose for the bulk order of hydroxychloroquine, which was made in the last several weeks? What proportion of the order was used to treat acute malaria, lupus, or rheumatoid arthritis? What proportion was used to treat COVID-19? Other conditions?

VA Response: VA continuously makes hydroxychloroquine purchases because it is used for non-COVID, non-malaria uses. However, in anticipation of a national hydroxychloroquine shortage, and significant public interest, and to mitigate potential disruptions to the supply chain, VA placed a series of bulk orders of hydroxychloroquine between February 1, 2020 and April 23, 2020. Those orders resulted in VA purchasing approximately 6,339,700 tablets of hydroxychloroquine to ensure that a sufficient supply across its facilities was available to meet non-COVID-19 and COVID-19 requirements. During this tracked time period, VA used about 18,000 of the tablets for COVID-19, which equates to 0.28%.

Since the beginning of the pandemic response, VA has treated approximately 8,800 patients with hydroxychloroquine. Of that number, approximately 7,500 were treated for non COVID-19 conditions and about 1,300 were treated for COVID-19.

Question 2: Is the VA continuing to administer hydroxychloroquine to patients for the purposes of treating COVID-19? If yes, how many veterans have been treated with hydroxychloroquine for COVID-19.

VA Response: VA has prescribed hydroxychloroquine to about 1,300 COVID-19 patients out of the over 10,000 Veterans treated for COVID-19 and will continue to do so in accordance with Food and Drug Administration (FDA) guidelines.

Question 3: Is the VA tracking and reporting detailed information regarding any serious adverse events related to the use of hydroxychloroquine?

VA Response: Data on safety issues including adverse and serious adverse events (which are the established terms for clinical trials) are collected and reported by the study investigator as a standard requirement as part of a regulated research activity. These regulations are put forth by the FDA and from the Common Rule governing the conduct of studies involving human subjects. Reports are sent to the Institutional Review Board and to Data Monitoring Committees.

Question 4: Does the VA plan on providing detailed information to veterans and their families related to the use of hydroxychloroquine for testing or treatment related to COVID-19?

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VA Response: VA continues to keep patients and families informed about possible side effects that have been linked to hydroxychloroquine, as with any other medical intervention.

Question 5: Which VA sites will or have received drugs from this recent order for the purposes of treating of COVID-19?

VA Response: All VA facilities either currently prescribe or can do so, as hydroxychloroquine is a standard drug in our inventory. It is distributed as needed to the sites that require it to treat several different conditions.

Question 6: Is the VA currently able to meet all needs for hydroxychloroquine for veteran patients with rheumatoid arthritis or lupus?

VA Response: VA is not currently having issues with hydroxychloroquine supplies. Prior to COVID-19, VA dispensed approximately 42,000 tablets of hydroxychloroquine each workday for non-COVID-19 treatments from its Consolidated Mail Outpatient Pharmacies (CMOP) alone. This treatment was primarily for rheumatoid arthritis and lupus. This volume is equivalent to over 1 million doses per month for dispensing and on-hand inventory for CMOP.

Question 7: Is there any informed consent at VA medical centers for receiving hydroxychloroquine? If so, is it written or verbal?

VA Response: Item 1.d on page 4 of VA's "off-label" use document describes when local facilities may require informed consent.

Question 8: Does the VA plan any further studies involving veteran patients regarding the use of hydroxychloroquine to treat COVID-19?

VA Response: VA's Office of Research and Development is planning a study to look at whether hydroxychloroquine will help prevent infection in Veterans who are potentially exposed to SARS- CoV-2/COVID-19. This study is scheduled for scientific review in late May 2020. If recommended for funding, the study will be overseen by the VA Central Office Institutional Review Board and will have an independent Data Monitoring Committee. VA is also in discussions with Novartis to have some VA facilities participate in a national multi-site clinical trial that will look at hydroxychloroquine, or hydroxychloroquine in combination with azithromycin, in patients with moderate and severe disease. These trials would follow all applicable FDA requirements in addition to VA policies for enrolling Veterans into studies. Preliminary indications from the company have indicated a start date near the end of May. Additionally, VA facilities and Veterans Integrated Services Networks (VISNs) are supporting their own clinical trials looking at

whether existing drugs and therapeutics can be repurposed for use in COVID-19 patients. The San Francisco VA Medical Center has begun a study to look at hydroxychloroquine or azithromycin to treat SARS-CoV-2 infection. Finally, the Atlanta VAMC is working with Regeneron Pharmaceuticals to assess the effectiveness of the drug sarilumab.

Question 9: Will the VA provide notification to Congress on any experimental tests being done on vets related to COVID-19?

VA Response: To be clear, this was not an experiment, nor is hydroxychloroquine an experimental drug. VA providers were following the Centers for Disease Control and Prevention (CDC) and FDA guidelines to prescribe a drug that has been in our inventory for years. This drug, as many others, was being prescribed "off label," with proper safety monitors and precautions taken, as we do with many other drugs, with guidance from CDC or FDA that is published for a new or additional use. Approximately 20% of all medications are prescribed in this manner.

Question 10: Were you or any official at the VA ever pressured by the White House, the Department of Health and Human Services or any other agencies to use hydroxychloroquine on veteran patients for the treatment of COVID-19?

VA Response: Neither the Secretary or any official at the VA was ever pressured by the White House or the Department of Health and Human Services or any other agency to prescribe hydroxychloroquine for COVID-19 patients in VA facilities. The idea that VA health care providers would make treatment decisions based on anything other than the best medical interests of our patients as individuals is preposterous. VA, like so many medical facilities across this Nation, is in a race to keep patients alive during this pandemic, and we are using as many tools as we can.