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## FOR IMMEDIATE RELEASE

The <u>American Academy of Clinical Toxicology</u>, The <u>American College of Medical Toxicology</u> and the <u>American Association of Poison Control Centers</u> Caution About Toxicity From Hydroxychloroquine and Chloroquine.

## McLean, VA -- March 30, 2020 --

There are currently no medications or vaccines proven to be effective for the direct treatment or prevention of SARS-CoV-2, the disease caused by COVID-19 coronavirus. 

1

Chloroquine and hydroxychloroquine are both FDA-approved drugs in the United States. Chloroquine is approved for the prophylaxis and treatment of malaria as well as amebiasis, and hydroxychloroquine is approved for both the treatment and prevention of malaria; chronic discoid and systemic lupus erythematosus in adults, and both acute and chronic rheumatoid arthritis in adults. On March 28, 2020, the Food and Drug Administration authorized emergency use of chloroquine and hydroxychloroquine for treatment of COVID-19 through the Strategic National Stockpile in adult and adolescent patients weighing 50 kilograms or more and hospitalized with COVID-19 for whom a clinical trial is not available or feasible. (See attached letter from the FDA)

In addition to being available as pharmaceutical agents, chloroquine phosphate is also widely available as an aquarium product used to treat parasite infections in fish. These products can easily be purchased in stores and online, primarily in powdered forms, and bulk packaging can contain large and potentially fatal

amounts of chloroquine.

Since there has been significant media attention surrounding chloroquine and hydroxychloroquine, a surge in prescriptions for these agents, particularly hydroxychloroquine has been noted. This has precipitated critical shortages of hydroxychloroquine, with many patients on this medication for rheumatologic disorders reporting that they are unable to obtain their medication. Additionally, if hydroxychloroquine is determined to be a viable treatment for SARS-CoV-2, shortages will limit the ability of providers to optimally treat critically ill patients. There have also been reports that providers have been inappropriately prescribing or hoarding chloroquine and hydroxychloroquine. In fact, some states, including New York, have prohibited the dispensing of chloroquine or hydroxychloroquine except when prescribed for an FDA approved indication or as part of a state approved clinical trial for a patient with documented COVID-19 infection. Other states have imposed restrictions limiting the number of pills or days supplied for prescriptions.

The American Academy of Clinical Toxicology (AACT), The American Association of Poison Control Centers (AAPCC) and the American College of Medical Toxicology (ACMT) want to provide information to both the public and health care professionals about the potential dangers and best practices for management of these medications.

Use of these medications should only occur under the direction of a medical provider, for an FDA-approved indication, as part of a trial for the treatment of COVID-19 or as part of an approved hospital protocol. Both chloroquine and hydroxychloroquine can result in severe toxicity, including death, when taken in excess or as a result of interactions with other drugs. Both of these medications can cause cardiac toxicity in the form of dysrhythmias and should be used with extreme caution in people with prolonged QT syndrome or who are on medications for heart rhythm problems, or medications that effect potassium levels in the blood, as the addition of chloroquine or hydroxychloroquine can increase the risk for fatal dysrhythmia. Azithromycin, which has been suggested by some to be used in combination with hydroxychloroquine for the treatment of SARS-CoV-2, may also cause QT prolongation, perhaps increasing the likelihood of cardiac dysrhythmia.

Chloroquine and its derivatives have a narrow margin of safety. In small children, exploratory ingestion of a single tablet can result in death. Toxicity is characterized by seizures, cardiac dysrhythmia, and dangerous changes in serum electrolytes, particularly potassium. Unfortunately, symptoms of toxicity occur rapidly and there is no proven antidote to treat patients who unintentionally or intentionally overdose on chloroquine and hydroxychloroquine.

It is important that you take only medications prescribed to you by a licensed healthcare provider for an FDA indication or an accepted protocol for use. Taking chloroquine or hydroxychloroquine that is not prescribed for you or from non-pharmaceutical grade sources is extremely dangerous. Since the start of the COVID pandemic, there has been at least one accidental death from chloroquine in a patient who ingested chloroquine obtained from aquarium cleaner.<sup>2</sup>

Prescribers should utilize chloroquine and hydroxychloroquine in accordance with FDA indications or when off label use is required, in accordance with clinical trial or institutional protocols. Self-prescribing or prescribing for family and friends is discouraged as is hoarding supplies of medication. In addition, we need to engage stakeholders, including healthcare providers, industry, and government to mitigate critical shortages of chloroquine and hydroxychloroquine to ensure an adequate supply to the patients that require these drugs for both acute and chronic therapy.

Toxicologists and poison information specialists are available to the general public and healthcare providers by telephone. If you suspect an exposure, contact your regional poison control center at 1-800-222-1222, 24 hours/7 days a week/365 days a year. Healthcare providers are encouraged to consult with a medical or clinical toxicologist when managing acutely poisoned patients.

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- 2. Fearing coronavirus, Arizona man dies after taking a form of chloroquine used in aquariums CNN.

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