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Lawrence R. Huntoon, M.D., Ph.D.
Editor-In-Chief

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President Donald J. Trump
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear Mr. President:

Members of the Association of American Physicians and Surgeons (AAPS), representing thousands of physicians in all specialties in all states, would like to express our gratitude for your leadership at this time of crisis. We are thankful for your calm, rational approach and for your recognition of the need to control our borders, support private enterprise, restore our capability to manufacture essential items such as drugs and medical equipment, and relieve medical practice and the economy as a whole from the burden of counterproductive taxation and regulation.

Faced with a novel virus that could overwhelm our medical system, we need rapid deployment of testing, adequate supplies of protective equipment, a surge capacity for hospital beds and medical manpower, and better treatment options.

For testing, South Korea is a hundred thousand tests ahead of us. Why is this, despite the immense capability that we have in industry and university laboratories? The entrenched federal bureaucracy in the FDA and CDC blocked these efforts until a window of opportunity had closed.

The federal government has a stranglehold on laboratory medicine because of the Clinical Laboratory Improvement Act (CLIA). Deviation from complex regulations could destroy a laboratory. SARS-CoV-2 testing is complex and fraught with pitfalls. We need independent efforts, not a government-imposed monopoly. In addition to testing for the virus, which has many false positives and false negatives, we need tests for acute (IgM) and convalescent (IgG) antibodies, so far not part of the approved regimen.

Our capacity to manufacture antibiotics, vitamin C, protective gear, and most other drugs was outsourced overseas decades ago. Your Administration needs to investigate the reasons for this, including the single-source contracts that benefit Group Purchasing Organizations (GPOs) and Pharmacy Benefits Managers (PBMs). These are enabled by a safe harbor in the Anti-kickback Statute and the failure of HHS to enforce the safeguards. (This is also a huge factor in high prices.)

The culpability of the FDA must not be overlooked. FDA has the power to shut down U.S. production of a pharmaceutical because of noncompliance issues that have no effect on safety or quality, such as exceeding a production quota or a paperwork oversight. Yet the FDA has no meaningful oversight of the production of the 90 percent of our medications that are made in China and other foreign nations. Nor has it responded to national security concerns about drug supply lines.

The FDA has a crippling effect on innovation, with \$1 to \$2 billion worth of requirements to bring a new drug to market. This still does not guarantee safety, as shown by the number of drugs that have to be withdrawn. Worse, the FDA is increasingly trying to expand its authority over the practice of medicine as in the “off-label” use of approved medications. Medical practice would be crippled if physicians had to wait years for the approval of each and every use of long-established drugs—or forever if no one saw the benefit in investing billions in the approval process.

We thank you for helping to make the long-established anti-malarial drugs chloroquine and hydroxychloroquine available for treating COVID-19. In our opinion, a “compassionate-use exception” is not needed because these drugs are already approved for another use. It would be needed for a not-yet-approved drug such as resdemivir.

The FDA wants to address this crisis with an FDA-approved vaccine, which takes more than a year to develop and test (and may not even prove to be safe and effective), not by inexpensive generic medication available now without control by the FDA.

Americans need the right to try. This should apply to all, not just to terminal cancer patients. It should certainly include safe interventions such as intravenous vitamin C, which the FDA is trying to ban. Note that 50 tons of vitamin C was shipped to Wuhan recently, and efficacy studies are underway there.

We appreciate your effort to ameliorate the shortage of medical personnel by allowing payment for telemedicine consultations, and your previous efforts to reduce the Medicare documentation burdens. Practitioners estimate that their productivity is decreased by at least 20 percent by electronic medical records, coding requirements, MIPS, and so on. Why should physicians, like other professionals such as lawyers, not set their own fees without being tied to thousands of codes invented by the AMA and the WHO? Why couldn't doctors get paid for treating COVID-19 without the AMA inventing a code for it? Why should insurers be dictating what care patients may receive, and what they may pay? Insurers should be transparent about what and how much they will reimburse, without interference in private arrangements. Likewise, government should not be dictating the terms of consensual arrangements.

A surge response is hindered by government licensure requirements. In federal facilities such as the Veterans Administration and correctional facilities, physicians may work if licensed by any state. In a national emergency, one state license should be sufficient for a physician to practice either in person or by telemedicine. A medical license might be honored in all states just as a driver's license is.

Please also consider how medical school graduates who are unable to find a residency program match (approaching 10,000 grads per year) can be put to work helping patients during this time of increased need for medical care. These physicians often have twice the amount of training as nurse practitioners or physician assistants but are impeded from helping patients in clinical care settings.

We applaud efforts at all government levels to allow medical staff to work without time-devouring, pointless regulatory shackles. After a temporary reprieve, we hope that you will consider permanent relief.

We appreciate your understanding of the severe harm caused by the Chinese government's lack of transparency in the early days. Please do not allow the U.S. to similarly constrain the flow of information from all sources. There are many unknowns. We need input from all who have experiences or ideas. We will not be able to sort out the errors from the facts until much more is known. Censorship should be anathema in these United States!

Most importantly, we need the right to try, and the right to communicate. While we need to minimize casualties from COVID-19, we must also survive as a constitutional Republic. We must not overlook old potential allies like the one George Washington used to protect his troops, the bark that contained quinine, of which chloroquine and hydroxychloroquine are analogs. Americans were protected against the malaria epidemic; the British were not. This unappreciated ally probably turned the tide at Yorktown.

Please let us know how we can be helpful.

Most respectfully,

A handwritten signature in cursive script that reads "Jane M. Orient".

Jane M. Orient. M.D.
Executive Director
Association of American Physicians and Surgeons

CC Sen. Mitch McConnell, Rep. Kevin McCarthy