EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

ASSOCIATION OF AMERICAN	
PHYSICIANS & SURGEONS,)
Plaintiff,)
V.)
FOOD & DRUG ADMINISTRATION;)
DR. STEPHEN M. HAHN, Commissioner)
of Food & Drugs, in his official capacity;)
BIOMEDICAL ADVANCED RESEARCH) No. 1:20-cv-00493-RJJ-SJB
& DEVELOPMENT AUTHORITY;)
GARY L. DISBROW, Ph.D., Acting)
Director, Biomedical Advanced Research) Hon. Robert J. Jonker
& Development Authority, in his official)
capacity; DEPARTMENT OF HEALTH &)
HUMAN SERVICES; and ALEX AZAR,)
Secretary of Health & Human Services, in	j
his official capacity,)
Defendants.)
	,

DECLARATION BY JEREMY SNAVELY

- I, Jeremy Snavely, hereby declare that:
- 1. I am over the age of 21 years and competent to make this declaration pursuant to 28 U.S.C. § 1746. I have not been convicted of a felony or a crime of dishonesty.
- 2. I am the Business Manager and Director of Regulatory Affairs of Plaintiff Association of American Physicians & Surgeons (AAPS) in this action.

- 3. The issues raised in this case are germane to the mission of AAPS, whose motto is "omnia pro aegroto" (meaning "all for the patient"), as the interference with patient access to hydroxychloroquine and physicians' ability to successfully prescribe are central to AAPS's principles and reasons for existing.
- 4. In my role at AAPS I frequently communicate with physician members of AAPS from across the United States, and based on these communications I have observed the following.
- 5. The actions by the U.S Food and Drug Administration (FDA) limiting the use of hydroxychloroquine (HCQ) have impeded the ability of AAPS members to practice patient-centered medicine.
- 6. Multiple members of AAPS have communicated to AAPS their inability to prescribe hydroxychloroquine (HCQ) for a full regimen to treat or prevent COVID-19, including but not limited to physicians in Western Michigan, Georgia, New Jersey, Arizona, and Texas.
- 7. The AAPS physician member who practices within the federal Western District of Michigan, identified as "Dr. John Doe" in the Complaint to protect him against retaliation, has been unable to successfully prescribe a full regimen of HCQ for patients in need of it, due to the FDA's restrictions on HCQ.
- 8. Numerous physician members of AAPS, including this "Dr. John Doe," reasonably fear retaliation against them by state medical boards based on

Defendants' irrational restrictions on HCQ along with the incorporation of the directive made to state medical boards by the Federation of State Medical Boards.

- 9. As I have learned from this "Dr. John Doe," patients of his have been additionally harmed by being denied access to a full regimen of the potentially lifesaving HCQ.
- 10. A physician member of AAPS in Georgia informed AAPS of the following: "I'm continuing to be thwarted ... in regards to prophylactic hydroxychloroquine for my nursing home patients. I had a nursing home ... patient pass away last night. The dead patient's roommate now is achy all over with a 99.7 temp."
- 11. We have heard from physician members of AAPS in Texas and Maine who are under investigation by their state medical boards simply for recommending and/or prescribing hydroxychloroquine to patients.
- 12. The Maine medical board included the FDA's March 28 Emergency
 Use Authorization (EUA) letter restricting HCQ to hospitalized patients as
 evidence that the physician was somehow practicing in violation of Maine statutes.
- 13. States issuing restrictions appear to be relying on guidelines issued by the Federation of State Medical Boards, which cite the FDA's EUA as a rationale for the imposition of state-based restrictions.

- 14. In addition, AAPS members have communicated with me concerning the status of the remaining HCQ in the Strategic National Stockpile (SNS).
- 15. Regarding the SNS, the *Orlando Sun Sentinel* reported on June 17, 2020 the following: "As of Monday, the government has distributed 31 million tablets of hydroxychloroquine to state and local health departments, hospitals and research institutions; 63 million tablets remain, according to Carol Danko, a spokeswoman for the Department of Health and Human Services."
- 16. A physician member of AAPS wrote to us to suggest that, "Hopefully [HHS] can issue [HCQ languishing in the SNS] in such a manner to those in need under medical care such as nursing home patients, other high risk [patients], [and] [p]eople in need of prophylaxis while working."
- 17. AAPS members are also concerned about the following conflicting statements issued by HHS related to the FDA's June 15, 2020 revocation of the March 28, 2020 EUA for HCQ.
- 18. HHS Secretary Azar stated in response to questions about the June 15 revocation: "If a doctor wishes to prescribe it [HCQ], working with a patient, they may prescribe it for any purpose that they wish to do so. And this [the revocation] actually removes a potential barrier to that."
- 19. However an announcement on the HHS website about the revocation states: "Now, hydroxychloroquine sulfate and chloroquine phosphate can only be

used for the treatment of COVID-19 as part of an ongoing clinical trial."

https://www.phe.gov/emergency/events/COVID19/investigation-

MCM/Pages/hydroxychloroquine.aspx

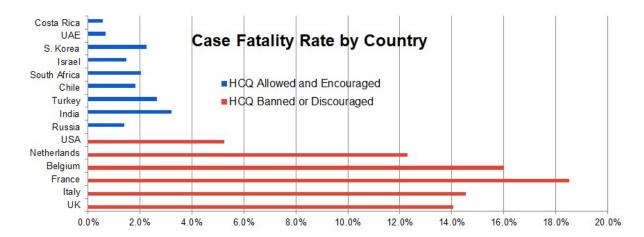
- 20. Separately, the FDA's "Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Hydroxychloroquine Sulfate and Chloroquine Phosphate" states, "FDA does not recommend using HCQ or CQ to treat hospitalized patients with COVID-19 outside of a clinical trial."
- 21. The above three statements from HHS entities present conflicting information about the ability of a physician to prescribe HCQ.
- 22. The unavailability of HCQ is impeding the ability of AAPS members to attend our meetings.
- 23. Our Workshop and Board Meeting scheduled for March 20 and 21, 2020, were cancelled. To my knowledge, the last time AAPS cancelled an event was in 1945 due to WWII travel restrictions.
- 24. The ability to hold the AAPS 77th Annual Meeting, scheduled for September 30 to October 3, 2020, is in jeopardy. Members have expressed to me their concern about travelling safely to the meeting and registration levels are trending significantly lower than in previous years.
- 25. Pre-registrations for the AAPS Annual Meeting are currently more than 90% lower than over the same period in 2019.

- 26. Our scholarship program to bring Medical Students to our meetings is similarly negatively impacted.
- 27. If HCQ were widely available as a prophylactic, and for early treatment, our members might be more comfortable attending our events.
- 28. I have reviewed COVID-19 data published on the worldometers.info/coronavirus website, and reviewed reports concerning HCQ policies. Worldometer is an independent and self-financed team of developers with no political, governmental, or corporate affiliation. I have found that HCQ use generally correlates with success in minimizing casualties from COVID-19:

Country	HCQ Policy	Percentage COVID-19 Deaths Per Case	COVID-19 Deaths Per Million in Population
United Kingdom	HCQ is discouraged and mostly unavailable	14%	628
Italy	HCQ's value was not known for the many initial casualties	14.5%	573
France	HCQ is officially disfavored	18.5%	454
United States	FDA interferes with access to HCQ	5.2%	370
Russia	HCQ is encouraged	1.4%	56
India	HCQ is used prophylactically	3.2%	10
Turkey	HCQ is used as early treatment	2.6%	59

Country	HCQ Policy	Percentage COVID-19 Deaths Per Case	COVID-19 Deaths Per Million in Population
Israel	HCQ is encouraged	1.5%	33
South Korea	HCQ is encouraged	2.3%	5

29. In a similar manner, I have developed the following chart concerning HCQ and mortality from COVID-19, to illustrate the impact of allowing/encouraging or banning/discouraging use of HCQ:



30. More than 25 articles since 1982 published in peer-reviewed medical journals have reported on the safety of HCQ, and these articles are included in the PubMed database as maintained by the United States National Library of Medicine at the National Institutes of Health.

The interference by the FDA with the access by AAPS members and 31. their patients to HCQ has a widespread effect and does not require the individual participation by members in this litigation to resolve.

I declare under penalty of perjury that the foregoing is true and correct. Executed on June 22, 2020. Jeremy Snavely