Commentary

The menacing assaults on science, FDA, CDC, and health of the US public

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While health authorities sounded early warnings concerning COVID-19 [1], the United States (US) government practised “pandemic politics” and escalated menacing assaults on science, including repeated denials of epidemic principles of mitigation and containment. The first on December 31, 2019 was that the virus would not enter the US. A second on January 20, 2020 following introduction of the first US case from Wuhan, China was that “the virus would not spread.” A third on February 26 was that the 15 cases would “go away” when temperatures climbed [2]. A fourth is continued and repeated denials of clear benefits of masking.

On April 27, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for hydroxychloroquine without randomized evidence [4,5]. The drug was approved 47 years ago primarily for young women with autoimmune diseases but there were no reliable randomized data about COVID-19 patients, many at risk of fatal arrhythmias, formulated from uncontrolled clinical observations [6]. Shortly thereafter, the trials all showed no benefit and some demonstrated harm. On June 15, the FDA withdrew the EUA but the US President continued to embrace the prescription of hydroxychloroquine which increased nine-fold, rendering the drug unavailable for many patients with autoimmune diseases. On August 24, the FDA again issued an EUA for convalescent plasma without any reliable data from large-scale randomized trials [4,5] but only one small trial, not surprisingly, showing no benefit [7].

Even more disturbing is the escalation of the politicisation of the US Centers for Disease Control and Prevention (CDC), formerly a role model for disease control and prevention activities worldwide. During COVID-19 the CDC issued reopening guidelines after initial lockdowns that lasted only until the epidemic curve flattened, violating their own principles to continue until cases and deaths drastically fell. On August 25, the CDC apparently updated guidelines excluding exposed but asymptomatic individuals from testing. Then, on September 17, it was revealed that White House officials edited the published guidelines without CDC approval. Thus, public trust and their longstanding stellar reputation need to be revived [8].

The government’s menacing assaults on science have led to the US suffering >203 thousand deaths compared with <3 thousand in South Korea after inflation for the six-fold difference in populations. Whilst the first cases were introduced on the same date in both countries, South Korea mounted an immediate and nationally coordinated effort to mitigate and contain COVID-19. In contrast, US responses were delayed, fragmented, and failed to emphasise masking, social distancing, and crowd avoidance. One tragic consequence is that the US is and will remain the epicentre of the pandemic accounting for >20% of global cases and deaths with <5% of the population [3].

If the past is prologue then pandemic politics concerning vaccines will lead to another premature EUA. In vaccine development, efficacy requires reliable data from randomised trials of a few thousand subjects over months. Safety, however, requires far larger sample sizes over a year or more [10]. In 1976, a swine flu vaccine was rushed to production and distribution and caused Guillain-Barre syndrome. Unfortunately, hopes and expectations of the US public have already been raised by unsubstantiated pronouncements [4,5].

Public health strategies of proven benefit may confer at least similar benefits to any vaccine [3]. Nonetheless, the US Attorney General has proclaimed lockdowns as tantamount to “house arrests” and the “greatest intrusion on civil liberties since slavery.” In addition, the menacing assaults on science decrease the ability to obtain the necessary reliable randomised evidence. Trust will continue to be eroded in other vaccines, as well as the FDA and CDC, leading to even more avoidable US deaths. In 2013 the Melinda and Bill Gates Foundation predicted a pandemic, most likely from coronavirus. In 2015, the US established a Global Health Security and Biodefense Unit. In 2016 the US was judged the best equipped country worldwide to contain and mitigate any pandemic. In 2018, however, the US government disbanded the entire team. Thus, the country judged best prepared for the existential threat was least prepared for the actual threat.

The continued menacing assaults on science threaten to turn the present tragedy into a future nightmare. Deaths may become more than ten-fold greater than the 61,000 US fatalities from influenza in 2018–2019 and comparable to the 675,000 American deaths from the Spanish flu in 1918–1919 [3].

One of the most consequential US presidential elections will occur November 3. The President recently proffered “herd mentality” to combat COVID-19 which would result in from two to six million

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avoidable deaths depending upon the timing and availability of an effective and safe vaccine applied to the majority of US citizens. The President has referred to the election as a referendum on himself but, in some senses, it is a referendum on science and democracy. This is due, in part, to the fact that, whilst publicly issuing repeated denials in February, he privately stated that COVID-19 “was more deadly than even your strenuous flu.”

In stark contrast to causing premature deaths, as competent and compassionate healthcare professionals, we must redouble efforts to combat pandemic politics and promote evidence-based clinical practices and discovery research. In the face of continued menacing assaults on science, healthcare providers should recall the Hippocratic Oath of “primum non nocere” and collaborate to enhance the health of the public throughout the world. As inscribed on the Richard Doll Building at the University of Oxford, “Death in old age is inevitable, but death before old age is not,” [9]—especially from COVID-19.

Declaration of Competing Interest

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Author’s contribution

All authors contributed equally with the exception that Drs. Alter and Hennekens conceived the idea and Dr. Alter wrote the first draft.

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