COMMENTARY

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Concerns About Our Public Medical Response to COVID 19

For 2 years now, I have been watching the official representatives of the medical profession publicly responding to the public health crisis posed by coronavirus disease 2019 (COVID 19). A retired primary care physician with experience in teaching, management, and research, I've been surprised and somewhat disturbed by what seemed to me to be obvious missteps, but I have been hesitant to go on the record myself when so many more highly regarded physicians have been involved in recommended policy. However, as the policies endorsed have so far proven to have less than ideal results, I think it worthwhile to make a few observations about issues which seem not to have been given sufficient attention to date, so that perhaps some of these issues will be front and center should we face similar challenges in the future.

I should make it clear that I do not plan to address the actual risk-to-benefit ratio of the various interventions I will be mentioning in passing. Although some of the references will inevitably espouse a variety of alternative interpretations of the scientific data concerning those interventions, I am not here endorsing any of them. I am interested rather in considering the overarching processes, not the quality of the individual measures being employed—as if we were looking back at a pandemic that resolved 10 or 20 years ago and each intervention's quality was already reliably established. Nor do I plan to consider why missteps might have been made, nor to make suggestions concerning how to approach the present pandemic. My goal is to focus on commonsense problems with our global approach, one at a time.

First, when faced with a new pathogen, it seems to be the better part of valor to begin by protecting the population against the worst case scenario: that the disease can be transmitted by droplet or fomite and recommending protective measures accordingly. To suggest that masks were unnecessary before that had been established seemed to me at the time and seems to me now to have been irresponsible. It is much safer to start with broad protective measures and narrow them once safety is proven than to start with narrow measures and broaden them when that doesn't work.

Second, it is a general primary care principle to use new medications and new technologies ("use it before it stops working or gets withdrawn from the market") only in a state of emergency and only when well-established medications and technologies are not effective or not available. The speed with which the new mRNA vaccines were developed was indeed impressive, and approving them for emergency use was eminently sensible; but it seems clear as well that a concerted effort to produce 1 or more traditional vaccines should also have been a priority. After 2 years, we still do not have a useful alternative to the Pfizer and Moderna vaccines in the United States. The Johnson and Johnson vaccine was also designed with a new technology (though a less disruptive one), was given as a single injection, was never really rigorously evaluated as a serious alternative, and was unfortunately found to be associated with Guillain-Barré syndrome. So far, there seems to have been little enthusiasm for Novavax at the Food and Drug Administration though the available data seem to suggest robust effectiveness and reasonable safety.

Third, it has been amply demonstrated that drug companies influence the research agenda[1] and that studies funded by drug companies tend to magnify positive outcomes concerning a company's products.[2,3] Unfortunately nearly all the studies that have established the effectiveness and safety of the 3 vaccines approved in the United States were funded by the companies that profit from their sale.

Fourth, it seems appropriate to evaluate the safety and effectiveness of the mRNA vaccines in large, state-of-the-art trials. However most of the studies done to date seemed designed to prove benefit, minimize risk, and encourage vaccine use, rather than to evaluate effectiveness and safety in an impartial, disinterested manner.[4-7] It is disconcerting to find that after 2 years of use we still do not have reliable evidence that the mRNA vaccines have saved a single life (i.e., that one year after vaccination a person vaccinated is more likely to be alive than one not vaccinated).[8-10] Clearly, the vaccines have prevented disease, hospitalization, and

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visits to emergency departments, and they are extremely likely to have decreased mortality as well, but, although we have endless studies of the relative value of various tests in diagnosis, we have none that are definitive about mortality.

Finally, science is best served by open communication—the interpretation of studies benefits from a full range of opinion, ideally expressed in journals and committee meetings and not in the media. However in the evaluation of mRNA vaccines and other COVID19 management options, non-"narrative" opinions seem to have been suppressed. Many people, some of whom have developed, supported, promoted, or lobbied for vaccinations all their lives have been hesitant about the COVID mRNA vaccines. Though some of them have been, until recently, respected practitioners, teachers, and researchers and many are fully COVID19 vaccinated themselves, their opinions have often gotten them removed from social media sites, and many of them say that they have had difficulty publishing, have been undermined,[11] or been threatened with loss of job or license; some say they were actually fired and that many of their colleagues have shared with them that they felt it risky to express their own opinions.[12-16] (Ironically, one doctor, Rick Bright,[17] was removed from his position for opposing the use of hydroxychloroquine, and another, Simone Gold,[18] was fired for promoting hydroxychloroquine.) That has led many to form or join organizations[19,20] through which to make their views known—and these organizations' views differ. (Just one of them, the Great Barrington Declaration[21] has been signed by more than 43,000 physicians; no, I'm not one of them.) It seems to me as I review the literature, that such opinions have only just over the past 2 or 3 months begun to appear in scientific journals and the mainstream press.

These missteps I've mentioned are, I feel, water under the bridge. The mRNA vaccines may yet justify the encomiums they have been given; and the medical advice given may prove to have been appropriate and may bring this pandemic under control. Nonetheless the failure to adhere to what seem to be routine principles of sound scientific inquiry and intervention have, I believe, harmed the reputation of organized medicine and public health and diminished the likelihood that the pandemic would come under control. It seems to me that we have, as a profession, taken unnecessary risks. And I am making a plea that in future we adhere to the principles that have created the medical knowledge that has been such a resounding success, doubling life expectancy and bringing disease after disease under increasing control.

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