The Pharmacist Activist

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"The fear of the Lord is the beginning of wisdom; all who follow his precepts have good understanding." Psalm 111:10a

Editorial

COVID-19:

Millions died! No One Is Accountable!

Are We Prepared for the Next Pandemic?

More than five years have elapsed since the beginning of the COVID-19 pandemic. The tragic consequences, mandates, restrictions, and the bitter and even hateful differences of opinion far exceed the ramifications of any event most of us have ever experienced. The millions of deaths and harmful events have resulted in vows from nations and healthcare agencies that we must prepare to prevent such a catastrophic experience from ever occurring again. Although the experience has advanced the knowledge about viruses and their transmission, and resulted in the development of new drugs and vaccines, questions persist as to whether the knowledge that has been acquired has been assembled into strategies and plans that will reduce the harmful consequences, or even if we are any better prepared, when the next pandemic arrives.

On various occasions I have voiced my views on aspects of COVID-19 in *The Pharmacist Activist*. Initially, I accepted and complied with the observations and recommendations of the individuals and healthcare agencies considered to have the greatest expertise. However, with increasing frequency, my knowledge, intuition, judgment, and reasoning made me question the declarations of the "experts." Although much remains unknown (e.g., implications of long COVID, the types and pathogenicity of variants/mutations), the 5-year "anniversary" of the start of the COVID-19 pandemic is an appropriate time to summarize what I have learned and my opinions and perspectives, a process that continues to evolve. There are many whose expertise and experience relative to aspects of the pandemic far exceed mine. I have learned from some of them and I have been deceived by some of them. Some will disagree with certain of the opinions I voice. I welcome their views and opportunities to discuss them.

My opinions and perspectives

- The virus that causes COVID-19 infection may be deadly for many.

The elderly, and younger individuals who are immunocompromised and/or have serious underlying illnesses,

are at the greatest risk of serious infection, hospitalization, and death.

- The virus that causes COVID-19 is similar to those occurring naturally in bats, but was modified in the laboratory to provide a "non-natural" structure that includes a spike protein.

- The COVID-19 virus was developed at the Wuhan Institute of Virology, and escaped via an accidental "lab leak."

- The World Health Organizations (WHO) and its member countries failed to hold the Chinese Communist Party (CCP) accountable for providing records and documentation (i.e., pertaining to the development, escape, and transmission of the COVID-19 virus) that were necessary to take actions that could reduce the transmission and consequences of what emerged as a devastating pandemic.

- The obsession of the "experts' and their agencies and government with the development of new antiviral vaccines and medications intimidated and prevented the evaluation of other treatment options.

- Ivermectin and hydroxychloroquine (HCQ) have value for the prevention and treatment of early COVID-19 infection.

Almost immediately following the first suggestions that these antimicrobial agents might be active against the virus, there was an avalanche of criticism from the "experts" and their organizations, and adamant statements that the drugs were ineffective, had a risk of serious toxicity, and must not be used. These statements were made without the support of science, studies, or evidence, at a time when no other drugs or vaccines had been demonstrated to be effective against COVID-19, and without other recommendations to treat the infection that could be transmitted to others and quickly be deadly for many.

Although I would not have anticipated that ivermectin or HCQ would be effective against COVID-19, I was very familiar with the properties and use of these two drugs from my teaching responsibilities. Ivermectin is a "miracle" drug for preventing river blindness that is caused by a parasite in countries in which it is endemic, and has subsequently been approved for the treatment of certain more common parasitic infections. HCQ was initially developed as an antimalarial agent but is most commonly used in current therapy for the treatment of lupus for which some patients have used it for decades. Both agents have been widely used and are considered to have minimal risk of serious adverse events. However, as interest in using HCQ for COVID-19 increased, its critics "discovered" the unlikely possibility of cardiac adverse events and declared it to be too dangerous (without supportive data) to recommend for COVID-19 infection.

Ivermectin is often used in veterinary practice as an anthelmintic (de-wormer), often in dosages that are considerably higher than those recommended for human use. An FDA message to consumers carried the title, "You are not a horse." As its off-label use increased for treating COVID-19 infection, the "experts" and their agencies and organizations intensified their criticism of the drug and warnings to prescribers, pharmacists, and other suppliers that they should not provide it, They cited increases in adverse events and visits to emergency departments (ED), without identifying the likely relationships to the substantially increased use because of the threat of COVID, including the use of higher-dosage veterinary products purchased as the products for human use became less available.

At an early point in the emerging COVID-19 crisis, the federal government purchased large supplies of HCQ tablets for the emergency stockpile. When the FDA provided emergency use authorization, its use was restricted to patients with infection that was already severe enough to require hospitalization, and for whom, other than support care, the only possibly effective intervention was a ventilator. HCQ was not effective in treating these already serious infections, and its critics used this "study" to conclude that HCQ was not effective against COVID-19 at any stage of infection, and that it should not be used at all. They refused to consider that the proponents for HCQ were recommending its use for prevention of infection in individuals who were exposed to the virus, and in the treatment of early infection.

For me, this continues to be the most baffling aspect of the COVID experience. WHY would the "experts" with excellent credentials and authority be so adamant in their opposition to the use of HCQ and ivermectin when other treatment options were not available and hundreds of thousands of in-

dividuals were at risk of experiencing a potentially deadly infection? I can't bring myself to believe that there are individuals who would place the health and lives of millions of people at risk while they wait for yet to be identified interventions that could provide the best possible treatments. Perhaps their obsession with the development of new antiviral medications and vaccines had a "limiting" effect on their consideration of other options.

However, things only WORSENED!

Advocates for the use of HCQ and ivermectin were also scientists and clinicians with expertise and excellent credentials, but with limited or no authority. They could reasonably be considered to be professional colleagues of the critics. However, the expert critics were not satisfied to have the experience considered as a difference of opinion among highly-qualified individuals. Some critics were determined to vilify and discredit the advocates for the use of HCQ and ivermectin, and alleged that they were conspiracy theorists, science-deniers, purveyors of misinformation, and worse. These critics who controlled the "official" agenda and decisions intimidated and threatened those who disagreed with them with penalties/sanctions that could include loss of hospital privileges, dismissal from residency programs, and/or suspension or revocation of their license. Such actions were taken against certain scientists and clinicians who persisted with their opinions and concerns, thereby jeopardizing their professional livelihood. This is a great injustice for those with the courage to challenge the directives and plans for the management of a pandemic about which so little was known about the virus, its transmission, and how to best, prevent, control, and treat it. The punitive actions taken against the "dissenters" should be immediately reversed and remediated! But there is no accountability to do so!

- Messages to the public by healthcare agency and government officials were later exposed as inaccurate and/or blatant deception.

Neither President Trump nor, subsequently, President Biden could be expected to have expertise regarding a response to a pandemic. Accordingly, they had to rely on the governmental healthcare agencies (e.g., CDC, FDA, NIH) and officials with the most expertise to recommend decisions, actions, and statements. The Presidents, and the public, were failed by the "experts," and deceived by some who failed to disclose and "covered up" pertinent information of which they were aware.

Many were responsible and at fault for the flawed and damaging decisions and mandates imposed on the public. No one was more aware, involved, responsible, and deceptive than Anthony Fauci, who viewed himself as the personification and voice of Science, and who insisted that science and evidence must be demonstrated to support decisions and actions that should be viewed as credible. He was an advocate for the belief that the COVID-19 virus was of natural origin, facial masking, social distancing, and closure of schools, businesses, and other events, none of which were supported by evidence of their validity. During this same time period he failed to disclose that he had authorized the provision of financial grants that were channeled to the Wuhan Institute of Virology to promote gain-of-function research that apparently resulted in the development of the COVID-19 virus that escaped and caused the pandemic.

- The credibility of terms such as "science," "settled science," "follow the science," and "evidence-based" is greatly diminished.

Individuals who use these terms to support their position or opinion should be asked to identify the specific science or evidence to which they are referring.

- Prepared in October, 2020, the Great Barrington Declaration (GBD; gbdeclaration.org) provided the most credible combination of expertise, reasoning, and common sense.

This approach of Focused Protection with the anticipation of herd immunity was designed to protect the most vulnerable (e.g., the elderly) while allowing those who are at low risk "to resume life as normal" (i.e., re-opening schools, businesses, and events). Prepared prior to the availability of COVID-19 vaccines, the GBD stated that reaching herd immunity "can be assisted by (but is not dependent upon) a vaccine." The GBD was prepared by three experts with impressive credentials and signed by thousands of medical and public health practitioners and scientists, as well as concerned citizens. I signed it immediately after I read it.

The World Health Organization and numerous other public-health and academic groups criticized the strategy, and the

American Public Health Association and other public-health groups in the U.S. warned in a joint open letter that the "Great Barrington Declaration is not grounded in science and is dangerous." Anthony Fauci and the then Director of the National Institutes of Health (NIH) criticized the strategy and demeaned the authors. In an ironic turn of events, Jay Bhattacharya of Stanford University, one of the three primary authors of the GBD, is now the Director of the NIH.

- The COVID-19 vaccines provide less benefit/protection than anticipated.

The most commonly used COVID-19 vaccines are Comirnaty (Pfizer) and Spikevax (Moderna). Both products are prepared using new messenger RNA (mRNA) gene-based technology with which there has been very limited experience but enables much faster production of vaccine products. Initially some suggested that these vaccines prevented the transmission of the virus and that "COVID-19 was a disease of the unvaccinated." There were widespread mandates that individuals be immunized and many individuals were terminated from their employment because they declined to do so. It was soon recognized that the vaccines did NOT block the transmission of the virus. In addition, variants of the virus that were resistant to the vaccines quickly emerged, significantly limiting the duration of protection provided by the vaccines and prompting the recommendations of "booster" shots.

I consider the use of mRNA technology to represent excellent progress. However, I feel that the potential benefits of the mRNA vaccines against COVID-19 have been greatly exaggerated and that we still know very little regarding their safety. It is essential that studies, data, and claims be critically evaluated. I recognize that there are statistical models that can be used to evaluate/predict almost everything. For example, a modeling study reported that within the 2-year period following the availability of the COVID-19 vaccines, the vaccines had prevented an estimated 18.5 million additional hospitalizations and 3.2 million deaths in the U.S. The numbers are very impressive, but what do they mean? They certainly don't provide evidence! Events that don't occur can't be counted, but do the numbers even have value as estimates? Pharmacists recognize this situation better than most. One of the most important responsibilities of practicing pharmacists is to identify and prevent medication errors, thereby avoiding adverse events and deaths. But drug-related adverse events, hospitalizations, and deaths are counted when they occur, and not if they didn't occur because of an intervention. The profession of pharmacy correctly recognizes that it would be inappropriate to claim that pharmacists prevent xx million hospitalizations and xx million deaths because pharmacists prevented errors.

- The short-term safety of the Pfizer and Moderna mRNA vaccines has not been adequately evaluated, and the long-term safety is not known.

There have been thousands of reports of short-term adverse events with the COVID-19 vaccines submitted to the Vaccine Adverse Events Reporting System (VAERS). To my knowledge, there has not been an extensive analysis of this information. The responses that are most commonly voiced are that the reports have not been confirmed or verified, and that there is insufficient information to demonstrate a cause-and-effect relationship. However, adverse events such as myocarditis and pericarditis with the mRNA vaccines, particularly in young males, were too common and concerning to ignore. Some tried to minimize their importance by noting that most of the cases were mild in severity, to which others responded that there is no such thing as *mild* myocarditis. A warning regarding these risks is now included in the labeling for Comirnaty and Spikevax.

The use of mRNA technology for preparing vaccines or for other purposes is sufficiently new that information is not available regarding long-term safety. Accordingly, the early identification of myocarditis as an unexpected risk that is not associated with other vaccines, should be considered an alert that there may be other risks of the new technology that have not yet been identified.

The individuals who are most vulnerable to potential longer-term risks with vaccines utilizing mRNA gene-based technology are pregnant women and their unborn children, lactating women, and young children as their systems mature and growth occurs. In my opinion, the potential risks of these vaccines outweigh the potential benefits in these individuals. These are not my decisions to make but, when asked my opinion, I recommend against the use of the COVID-19 mRNA vaccines in pregnant and lactating women and in children who do not have underlying conditions that place them at risk of severe complications if they experience COVID-19 infection.

- Inaccurate information provided by government and healthcare officials, as well as conflicting statements from scientific and clinical experts have seriously eroded the public trust.

Many have lost family members and close friends to COVID-19, have been disadvantaged by required closures/cancellations of schools, businesses, and events, and many strongly resent the mandates to be immunized with vaccines in which they do not have confidence and are concerned about risks. There is strong distrust in government, science, and healthcare leaders who are expected to provide the expertise and guidance to control the destruction of the pandemic. There were huge expectations when the COVID-19 vaccines became available in late 2020 although some strongly objected to the mandates to be immunized and other restrictions. The enthusiasm for a "solution" to the devastating pandemic and the widespread immunization mandates resulted in a large fraction of the population being immunized. As experience with the vaccines was acquired and the emergence of resistant variants of the virus were identified, the immunization recommendations were extended to include booster shots and then annual COVID-19 immunizations. Less than five years after the vaccines became available, the estimated compliance with the current recommendations is less than 25%.

The distrust of the public in the government and healthcare leadership has become the most important challenge in responding to COVID and future public health crises, as well as compliance with conventional vaccine recommendations. Differences of opinion among "experts" can be positive and beneficial. However, when the differences become angry, vitriolic, and hateful, the public does not know whom to believe and they place their trust in family members and others in whom they have the greatest confidence.

My experience

Initially, I was very impressed with Anthony Fauci. I think he is intelligent and his discussion of the challenges were confident, authoritative, and persuasive. I trusted him, although I was puzzled that he was so adamant that the virus was of natural origin (bats) and his determination to discredit HCQ and ivermectin and their advocates. I was too trusting, and not confident enough in my curiosity and reasoning, and knowledge that was much more limited than his. Through listening, reading, and learning, I came to the personal conclusion that he knew much more than he was revealing, and that he was deceiving world and U.S. government leaders and the public. He retired on his own terms, but he and those with whom he colluded should be held accountable.

I was compliant with the recommendations and received the first two doses of the Moderna COVID-19 vaccine three weeks apart, and then the first recommended booster shot. I experienced three episodes of COVID-19 infection, two of which were treated with nirmatrelvir plus ritonavir (Paxlovid) and the third with molnupiravir (Lagrevio). I tolerated the vaccine doses and the antiviral medications well, although many others were less fortunate. I do not have confidence that additional COVID-19 immunizations are of value for me, but have received influenza vaccine annually, pneumococcal vaccine, and the recommended two doses of Shingrix.

The Current Battleground in the COVID War

Several months ago the Centers for Disease Control and Prevention (CDC) discontinued its previous recommendation that healthy children and healthy pregnant women be immunized with a COVID-19 vaccine. It now recommends that parents of children aged 6 months to 17 years speak with their physicians about the benefits and risks of the vaccine.

The CDC has used an Advisory Committee for Immunization Practices (ACIP) with 17 experts as members. Because some of these individuals were alleged to have conflicts of interest involving vaccine manufacturers or others, and many had participated in previous decisions with which members of the new administration disagreed, all 17 members of the ACIP were dismissed and replaced by 8 new experts. I do not know any of the 25 experts but am confident that ALL of them have impressive credentials and extensive expertise, even though they hold very different opinions about the use of certain vaccines. It is tempting to suggest that we lock all 25 of them in a conference center and release them only when they have developed consensus statements. However, that would probably be too dangerous, and it is too late to do that. Advocates for the 17 experts who were dismissed have vilified some of the new appointees, alleged that the healthcare system and agencies are being sabotaged and lives are being placed at risk, and have filed lawsuits.

On August 27 the FDA approved the 2025-2026 formulas

for the mRNA vaccines Comirnaty and Spikevax, and the protein-based, non-mRNA vaccine (Nuvaxovid – Novavax/Sanofi). All three products are indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS CoV-2), and are approved for individuals who are 65 years of age and older. All three agents are also approved for individuals 64 years of age and under with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19, although the approved minimum age is different for the three products. Nuvaxovid is approved for individuals 12 years of age and older, Comirnaty for individuals 5 years of age and older, and Spikevax for children 6 months of age and older. Comirnaty had previously been used under an FDA emergency use authorizations in children as young as 6 months, but that authorization has now been revoked.

Previously, it was recommended that all individuals 6 months of age and older receive an annual COVID-19 immunization. Therefore, some have been highly critical of what they view as restrictive/limited wording for the new vaccine formulas. However, the regulation of the practice of medicine, pharmacy and other health professionals is the responsibility of state regulatory boards, and not of the FDA, CDC, or other federal agencies. As with other vaccines and medications, the COVID-19 vaccine may be used off-label when the health professional and the patient or parent consider that to be the best course of action. Thus, the use of the vaccines has not actually been restricted or limited as critics have claimed.

The cost of immunizations that are recommended by the ACIP has been covered by government and health insurance programs and there is a valid question as to whether some programs will deny coverage for individuals whom they don't consider to have met the criteria of the new indications/approvals labeling. However, this is a reimbursement issue that should be addressed separately.

In the meantime, the criticism escalates with the American Academy of Pediatrics recommending that parents get all children ages 6 months through 23 months immunized against COVID-19, and that children ages 2 to 18 be immunized if they or individuals in their household are at high risk of COVID-19. The American College of Obstetricians and Gynecologists has recommended that all pregnant and lactating women be immunized.

Whereas agencies such as the FDA and CDC have legislatively-defined authority, organizations of health professionals do not. They can and should voice opinions, but the dissemination of recommendations that are not consistent with those of the agencies with authority are counterproductive and confusing. Organizations such as those of physicians, pharmacists, or public health scientists consider themselves to be objective and unbiased. However, if they receive grants, sponsorships, or other financial support from companies that make COVID vaccines or otherwise have a vested interest in their widespread use, their claims to be unbiased are not credible.

Initially I trusted the information and recommendations we were being provided but Anthony Fauci deceived me and others. In the early stages of the pandemic, there were two individuals who particularly impressed me by the way they integrated their knowledge with sound judgment, reasoning, and common sense in their statements and interviews. Jay Bhattacharya is now the Director of the NIH and Marty Makary is now the Commissioner of the FDA. I have confidence they will not deceive us.

Are we prepared for the next pandemic? NO!

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