



# The Pharmacist Activist

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**“God is our refuge and our strength, an ever present help in trouble.”** Psalm 46: 1

Editorial

## **Our Healthcare System is Broken!**

### **It has Worsened over Decades on My/Your Watch**

**New Experts/Leaders with Different Ideas Should be  
Provided the Opportunity to Improve It!**

### ***A Lesson from the DES Daughters***

**T**he advances that have been made in improving health care during the last 30 years have been remarkable. Exceptional advances have occurred in characterizing and diagnosing previously unrecognized diseases, increasing sophisticated surgical procedures and the use of technology, and developing and administering new medications. This should be an era of celebration of these accomplishments that maintain and improve health, and that increase the quality and duration of our lives. However, if asked to choose a response to the statement, “Our healthcare system is broken,” the vast majority of the American public and healthcare professionals and caregivers would respond, “Strongly Agree” or “Agree.” This may be one of a very few topics in which the opinions of Americans approach unanimity. But why is there such a disconnect between the accomplishments and the extent of the “brokenness” that many would identify as the reality of our healthcare system?

Dozens of reasons could be identified but I would suggest the following as among the most important:

- The health professions have lost control of their professional destiny, or allowed others to assume it.
- The leadership and members of individual health professions are not unified in identifying and achieving the purposes, plans, and strategies for their profession. The communication and collaboration of two professions with each other is even less likely.
- The differences of opinion and the adamant positions of “experts” within an individual profession are barriers to accomplishment and progress. When the positions of one or more groups of “expert” scientists, researchers, academicians, clinicians, legislators, and regulators

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are challenged by “experts” with opposing and/or competitive positions, the consequences are gridlock, and the lack of progress.

- Health insurance companies, pharmacy benefit managers, and government agencies determine and control the policies and decisions regarding healthcare programs and services, as well as the decisions made by healthcare providers for their individual patients.
- The economic controls and restrictions on the provision of healthcare services limit the amount of time, communication, counseling, and the “personal touch” healthcare professionals can provide for individual patients.
- Medical errors, and prescribing, dispensing, and other preventable drug-related problems harm or kill tens of thousands of patients each year.
- The complexity and lack of transparency of healthcare benefit plans, coverage, and costs are extremely difficult to understand and navigate, and are barriers to revision and the development of innovative and better options.
- The cost of the current healthcare system is excessive and unsustainable.
- There is rampant fraud, abuse, and waste in the healthcare system.

### **For how long has the healthcare system been broken?**

Most responses will vary from years to decades. For the last 30 years I have been writing editorials for several publications, most recently in *The Pharmacist Activist* for the last 20 years. Most of my commentaries over that period of time voiced concerns and criticisms with respect to pharmacy-related issues, many of which also pertained to the larger healthcare system. Recent events have enhanced my perspective to recognize that the current state of “brokenness” has occurred on “my watch” and “your watch” (with a pass for the student pharmacists and recent graduates). I recognize that I have *not* been effective in stating my opinions and recommendations, and that I have not been persuasive, bold enough or critical enough of the individuals and organizations which

I consider most responsible for the current problems.

I accept my share of the responsibility for not doing more and not being more effective in placing our profession in a better position for those who follow us. Pharmacy and every other health profession have heroes whose accomplishments have been exemplary. Even with their leadership, the “brokenness” continues to exist and worsen. With millions of health professionals and thousands of healthcare associations, colleges, and regulatory boards it is too easy to conclude that no individual or organization is at greater fault than others for the failures of our healthcare system. However, just as there are heroes in every health profession, there are those who are destructive and they must be challenged. It is also important to recognize that our broken healthcare system is “bipartisan” and has occurred and worsened through both Democratic and Republican administrations and authorities.

### **Is our broken healthcare system improving or worsening?**

I and many others would respond that our broken healthcare system is worsening! Those of us who have observed this downward spiral over several decades, and the much smaller number who have tried to reverse it, have *failed*, notwithstanding good intentions. The decline in the public trust in the healthcare system, professionals, and agencies accelerated during the COVID-19 pandemic as reflected, in part, by the fact that less than 25% of those for whom the COVID-19 vaccine has been recommended choose to receive it.

### **The 2025 changes**

As new officials have been elected and appointed to important positions of responsibility during 2025, they have brought some new/different ideas for addressing the problems of our healthcare system. These are the individuals who now have the authority to appoint individuals in whom they have confidence, and to study and implement new policies and decisions. How have much of the “established” healthcare community and many of its experts, as well as much of the media, responded? With strong criticism of the new “officials/experts” and their ideas and refusal to even consider different points of view! The critics might as well be sending the message: “We are the ones who are most knowledgeable and experienced (and responsible) for this broken and worsening healthcare system, and we reject other experts and their opin-

ions.” Much of the criticism has been directed against HHS Secretary Kennedy but also against FDA Commissioner Mary and NIH Director Bhattacharya.

## The new ACIP

The prior advice of the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) for the COVID-19 vaccines included recommendations that it be administered to all individuals 6 months of age and older including young children and women who were pregnant. Secretary Kennedy’s dismissal of all 17 members of the ACIP was a flashpoint for criticism of the removal of experts from the immunization recommendation process. I am not aware of any questions about the credentials of these individuals, but there are some with alleged conflicts of interest, and they were the individuals who prepared the recommendations for the COVID-19 vaccines which most of the public do not trust.

Secretary Kennedy subsequently appointed experts to a new ACIP, and has recently appointed five more. However, some of the previous CDC and other health agency officials, as well as some of the established healthcare community, have characterized the new appointees as unqualified, and holding dangerous and unscientific views. The frenzy of criticism escalated when it was anticipated that the new ACIP would revise the previous recommendations for administering COVID-19 vaccines. Even before the new ACIP met, several medical associations (American Academy of Pediatrics [AAP], American Academy of Family Physicians [AAFP], American College of Obstetrics and Gynecology [ACOG]) announced that they would issue their own guidelines for use of the COVID-19 vaccines. Some pharmacy associations have also voiced criticisms. Some individual states, as well as coalitions of several states and other groups are developing their own recommendations. Although these associations may have prominent and loud voices, they have no authority, but their actions confront and undermine those of a single national authority, and are confusing and divisive.

A primary concern that resulted in the dismissal of the members of the previous ACIP was whether some individuals had alleged conflicts of interest. I am surprised that I have not heard more questions as to whether the healthcare organizations and others who are critical of the leaders of the healthcare agencies and the new ACIP receive grants

or other funding from Moderna and Pfizer which make the messenger RNA (mRNA) COVID vaccines. If they do receive such support, they should be required to disclose it.

## Encouragement!

In spite of the continuation of criticisms of proposed and anticipated changes, there are reasons for encouragement. The new ACIP met on September 18-19.

- For the first time, a pharmacist has been appointed as a voting member of the ACIP. Congratulations to Pharmacist Hillary Blackburn, Director of Medication Access and Affordability at AscensionRx.
- It is my understanding that the meeting provided the opportunity for voicing different opinions, questions, debate, and even changes/reversals of preliminary decisions.
- The new ACIP voted to NOT make a recommendation regarding the COVID-19 vaccines. Rather, it advised individual decision-making (also referred to as shared clinical decision-making) involving the individual with a healthcare provider. (This approach should support communication of individuals with pharmacists or other healthcare providers to assess their risks of serious complications if they experience COVID-19 and whether the use of the vaccine would be advantageous).

I am encouraged by and support these decisions.

I am a member of the established pharmacy and healthcare community. Although I like to think I have been open-minded and voiced dissent when I have considered it appropriate, I also recognize that our healthcare system is broken and has worsened on my watch over decades. The new leadership has been in office for less than a year, and I am encouraged and impressed by what I have observed and learned. Our established pharmacy community has had its opportunities and failed to reverse the brokenness of our healthcare system. Our pharmacy associations and leaders should abandon their rejection and even personal criticism of those with differing opinions. I urge that we focus on ways to collaborate with the new leaders in discussion and debate that will move us forward toward our common goal of optimizing our healthcare system.

## A continuing lesson from history

The position of the new ACIP regarding the COVID-19 vaccines has been criticized by some as a non-recommendation that will increase confusion and vaccine hesitancy of the public. Although the opinions and recommendations of experts are valued and important, a universal “one recommendation fits all” guideline, or mandate as was often the situation during the pandemic, is a disservice for many. The lack of consensus among experts/leaders further confirms the wisdom of an approach that encourages consultation between patients and their individual providers. This discussion of the individual’s medical history and the potential benefits and risks of administering the vaccine will enable the *best and personalized* decision that can be made.

In the mid-1970s, I learned of a tragic situation that demonstrated the impossibility of anticipating the long-term safety/consequences of pharmaceutical products. The experience is designated “DES Daughters,” Learning about it created an indelible perspective and caution with respect to all pharmaceutical products, and has also influenced my views on the use of the COVID-19 vaccines.

Diethylstilbestrol (DES) is a synthetic estrogen that was initially marketed 85 years ago. From the period of approximately 1940 to 1970, it was prescribed to prevent spontaneous abortions and miscarriages, as well as certain other pregnancy complications. In the early 1970s, research studies suggested that exposure to DES in the womb was associated with the subsequent occurrence of certain cancers in the cervix and vagina. It is estimated that more than 5 million women (DES Daughters) were exposed to DES because their mothers (DES Mothers) had been treated with the drug while pregnant. The FDA issued warnings against using it during pregnancy.

Subsequent studies have identified other increased risks for DES daughters such as breast cancer and reproductive issues. DES mothers also have a higher risk of breast cancer. The risks associated with the use of DES during pregnancy are not limited by gender or generation. DES sons appear more likely to experience genital abnormalities (e.g., undescended testicles, testicular infection) and heart disease. DES daughters or DES sons may experience gene changes that they can pass on to their children (DES Grandchildren) who may also be at greater risk of adverse events. Research

studies of the harmful effects of DES when used during pregnancy are continuing, but are severely limited because of the difficulty in identifying mothers who were treated with DES more than 50 years ago and locating their medical records with information such as dosage and duration of treatment.

The information provided above is just a very brief summary of this topic. I hope that some readers will have the time and interest to learn more about the unanticipated harm of a medication that was developed decades before the harm was recognized. The websites for the American Cancer Society and the National Cancer Institute are excellent sources of additional information.

## A mentor’s experience

It is my impression that very few health professionals know about the DES Daughters experience. I did not become aware of it from any pharmacy course or CE program I attended. The late Linwood Tice was one of my esteemed mentors and friends. Following his retirement from his position as Dean of the Philadelphia College of Pharmacy in 1975, he was asked to serve as an expert witness for DES daughters who were plaintiffs in a lawsuit against the many pharmaceutical companies who marketed brand and generic DES formulations that were alleged to have been prescribed for their mothers. Linwood was one of a very few individuals who had the expertise about drugs, including DES, and the companies who were marketing it and the conditions for which its use was being promoted during the 1940-1970 period of time. Although Linwood had participated as an expert witness in other lawsuits, it was primarily for the purpose of defending pharmacists and pharmaceutical companies when he felt they were being unfairly sued. He initially felt he should decline participation in a lawsuit against companies in which he had many friends and former students. However, he was asked to meet with several of the DES daughters who were plaintiffs and review the preliminary defenses of the companies. He was heartbroken as he learned about their suffering, anxieties, and uncertainties, and dismayed by the “defenses” of the pharmaceutical companies as they attempted to absolve themselves from any responsibility. He agreed to serve as an expert witness for the DES Daughters, and he shared with me his experiences of being deposed by many attorneys representing the defendant pharmaceutical companies.

## Balancing benefits and risks

Whether it is a new drug (e.g., those with a novel mechanism of action that alter hormonal, immunologic, or genetic functions), a new vaccine, a new technology for developing pharmaceutical products, gene editing or gene therapies, or new radiation imaging or treatment strategies, we know nothing or little about the long-term risks (or the duration of benefits) of these innovations. With the use of these new drugs and innovations over an extended period of time, however, we often become aware of risks that were not recognized when the drug or other innovation was first approved. There have been numerous situations in which the labeling has been revised to add warnings and/or contraindications, and some products have been withdrawn from the market because of toxicity concerns.

## Implications for COVID-19

Regardless of the continuing questions and disagreements about all-things COVID, it has been the most devastating disease challenge of our lifetimes. We already knew about coronaviruses and other respiratory viruses, but not about characteristics such as the spike protein that make COVID-19 different. The recognition of “long COVID” is also a factor that distinguishes COVID-19 from other common respiratory infections that are typically of short duration. Efforts were initiated to develop new antiviral drugs that are active against the COVID-19 virus, but most experts were of the opinion that the development of vaccines was the best strategy to prevent infection and control the pandemic. Several of the vaccines that were developed (Comirnaty, Spikevax) utilized a new messenger RNA (mRNA) gene-based technology with which there had been little previous experience. The urgency to control the pandemic combined with the new technology resulted in the development, clinical evaluation, approval, and availability at an unprecedented pace. The elected leaders and officials of healthcare agencies and organizations embraced the availability of the vaccines and many advocated that their administration be mandated for almost all of the population. Many individuals who voiced concern about insufficient efficacy and safety information, were ostracized and threatened with a loss of their professional credentials. Dissent was not tolerated, and even raising questions was viewed as spreading misinformation.

I hope that there will be no long-term harmful consequences

of using the mRNA COVID-19 vaccines. However, that possibility can't be excluded, particularly with the utilization of a new gene-based technology. During the approximately five years since the COVID-19 vaccines were developed, approved, marketed, and widely administered, there are still important questions that have not been resolved:

- The clinical trials of effectiveness and safety were of short duration and showed weak, variable, and transient effectiveness.
- The type and incidence of adverse events have been insufficiently evaluated, assessed, and communicated to patients. This is the situation with the short-term use of the vaccines. There is essentially no monitoring for consequences of longer-term use and this possibility is seldom mentioned.
- The universal recommendations for the COVID-19 vaccines for everyone 6 months of age and above places millions of individuals at potential risk IF unanticipated risks are identified at a later time. While recognizing the long-term harm for each individual victim of the experiences with DES and certain other medications, the number of patients treated with those medications is much smaller than the number of individuals who have received and will receive the COVID-19 vaccines.

The risk of experiencing a serious COVID-19 infection is very low in young children, and highest in older adults. Some in the latter group have developed immunity against the virus from experiencing the infection or receiving the vaccine. I applaud the new ACIP position of individual decision making. I am sufficiently confident in what I have learned and my assessment of the benefits and risks of the mRNA vaccines that, if I am asked by family members, friends, pharmacists, or others for my opinions, I provide the following response:

The mRNA vaccines should be used only in patients who have underlying medical disorders or other factors which would place them at high risk if they experienced COVID-19 infection. The vaccines are not necessary to use in healthy children, during pregnancy, or in other adults.

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**Editor's Note:**

I received numerous responses to my August editorial regarding the COVID-19 pandemic, and I am pleased that most were supportive. One supportive and one critical response are included below to provide additional perspectives on this topic of continuing importance.

Response from pharmacist Lowell Anderson, Arden Hills, MN:

Thanks Dan. You say we are not ready for the next pandemic. I agree -- we learned nothing from the SARS epidemic of a few years ago. We didn't even replenish the supplies that we used. To learn from COVID we must look critically at its management and in the context of how other countries did it. I fear that the "science community" will frustrate those efforts.

You list some people whose judgement you trust. I agree with you on these and would add Adm. Redfield and Dr. Atlas, who were sidelined by Fauci. I had always respected Francis Collins, but that changed when he directed the sequestering of the Barrington document.

I think science took a hit -- science by its very nature is never settled. As we learned more during COVID our leadership never said that some of the early advice is no longer valid and this is what we have learned (e.g., masking, distancing, closing schools).

I think the profession of Public Health took a hit. Public health as I understood it was the total health -- physical, mental, environmental, economic. Yet during COVID public health seemingly was only about epidemiology. So we suffered in the other areas.

One of the scariest things was how easily we as citizens willingly gave up many of our constitutional rights. The Bill of Rights was suspended in MN for 16 months by a unilateral action of our governor. No one complained. Politicians rail on about protecting our constitutional rights yet many were the first to suspend them.

There are people such as yourself who are now spotlighting the good and the bad of the management of the Pandemic. I just hope that they get printed and read.

Thanks again for your thoughtful and balanced Activist.

Response from a Colorado pharmacist who requested that his name be withheld:

I am a retired pharmacist responding to your August newsletter. First, I have never understood how ivermectin and hydroxychloroquine ever got started as treatments for Covid. It seems extremely unlikely to me that either drug could be effective against the COVID virus. I realize that sometimes drugs can have unapproved uses; just not sure how anyone would choose those two.

Second, you seem to have a vendetta against Fauci. While I agree somethings could have been done differently, I think Fauci did a pretty good job; especially pushing back against Trump and others in his administration who were suggesting using injections of bleach! I think it's more important now to get rid of RFK, Jr and his conspiracy theories before he totally destroys vaccination programs and disease research. He is a total disaster.

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