The Pharmacist Activist

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"For I know the plans I have for you, declares the Lord, plans to prosper you and not to harm you, plans to give you hope and a future." Jeremiah 29:11

Editorial

SEPTEMBER 11, 2001 - We Must Not Forget!

The Deaths and Grief for so Many Have Been a Source of Courage, Inspiration, and Faith for Many More

I write this on September 11, 2023. Last evening I watched the "60 Minutes" coverage of the tragedy of 9/11 and the bravery and loss of the firefighters and other first-responders. This morning I watched a man named Frank Sillers being interviewed. His brother was a firefighter who lost his life on 9/11, and Frank has established the "Tunnels to Towers Foundation" that has provided exceptional support for the families of 9/11 victims and others.

The tragedy of 9/11 also has a personal connection for me. I first met Jennifer Trebino when she was a student of mine at the Philadelphia College of Pharmacy and Science (PCPS). I did not stay in communication with Jennifer following her graduation in 1989. But many years later, in 2003, I read an article in the Philadelphia Inquirer newspaper about a book written by 9/11 Widow Jennifer Sands who had attended PCPS. I was not familiar with the name "Sands" and I had numerous students with the name "Jennifer." But it did not take long for me to discover that she was the former student I knew as Jennifer Trebino.

Jennifer was employed as a pharmacist at Briarmill Pharmacy in Brick, New Jersey. Through a dating service she met Jim Sands. On that first date, Jennifer and Jim realized that they lived only blocks away from each other for 30 years, but they never knew each other. They subsequently married and continued to live in Brick, NJ.. Jim worked for Cantor Fitzgerald in Manhattan, his office was in the North Tower of the World Trade Center. Every morning when Jim left for work,

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Jennifer (who would not have described herself as religious) would briefly pray to God for safe travel for Jim. Jim left for work at 6:00 am on Tuesday, September 11, 2001, but Jennifer was not working that day. However, shortly before 9 am, she called the pharmacy to be sure there were no questions pertaining to the work she had completed the previous evening. Her friend who worked as a cashier immediately asked if she and Jim were ok. Then her pharmacist friend Rich quickly got on the phone and asked, "Jen, what floor does Jim work on?" Jennifer responded, "The 103rd floor…why?" Rich then informed her that a plane had just hit the World Trade Center.

Jim died that day – murdered by terrorists – and not a single trace of him has ever been found. Stunned with grief and pain, Jennifer's first reaction was anger at God since she had prayed for safe travel for Jim. Her grief continued…but with the passing of time, the support of family and friends, and a remarkable series of events, Jennifer developed a strong faith in God and is now an acclaimed Christian speaker and author.

After reading the Philadelphia Inquirer newspaper article, I contacted Jennifer…and since that day, Jennifer, my wife Sue and I have become close friends. We meet several times a year, including at pharmacy conferences and events at which Jennifer is speaking.

Jennifer's website is www.jennifersands.com and her trilogy of books (published by The Olive Press, Savannah, Georgia) are *A Tempered Faith, A Teachable Faith*, and *A Treasured Faith*.

I plan to read these books again this week and we look forward to our next visit with Jennifer later this month. Whether or not you have a faith in God, I encourage you to also read these inspiring books.

Two days ago I was speaking with a pharmacy friend. Her daughter had become aware that the school her children attend did not have plans to observe the anniversary of 9/11 today. Not even a single moment of silence. Her daughter and her husband had their children watch a documentary about 9/11 prior to the anniversary, so that they would be prepared to share what they learned and ask questions at their school today. Sadly, there was no recognition of this event that forever changes our nation and her world. We must not forget!

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The Decongestant Debacle and the Dysfunctional FDA

Many of us remember phenylpropanolamine (PPA). It is a sympathomimetic amine (i.e., amphetamine-like) that was administered orally, available without a prescription, and used as a nasal decongestant, but much more often as the most widely used nonprescription appetite suppressant. Recent pharmacy graduates are not likely to know about it because it was removed from products in the U.S. following continuing contentious discussions involving the FDA, pharmaceutical companies and scientists, and others regarding the suggested risk of hemorrhagic stroke in women. The number of these events was very small in the context of how frequently it was used by so many, and debates reg ard-ing its safety and risk continue long after the drug was removed from the market.

Ephedrine, pseudoephedrine, and phenylephrine are also sympathomimetic amines that have been used as nasal decongestants, and certain other conditions. The availability of ephedrine has been significantly restrict-

ed because of concerns about misuse (e.g., to enhance athletic performance) and adverse events. Along the way, it was recognized that pseudoephedrine could be easily converted to methamphetamine, a dangerous and addicting stimulant that has been widely abused. Criminals and others, typically with little or no science background but who often seem to be many steps ahead of the FDA and DEA, prepared and widely sold methamphetamine. Following lengthy deliberations involving the FDA, DEA, Congress, and other interested parties, the Combat Methamphetamine Epidemic Act of 2005 (CMEA2005) was approved and subsequently incorporated into the Patriot Act in 2006. This act bans the over-the-counter (OTC) sales of products containing pseudoephedrine, and restricts their nonprescription availability to behind the counter (BTC) sales of monthly quantities to a designated maximum number to purchasers who present photo identification. Pharmacists and our organizations have unsuccessfully requested for decades that a class of drugs be established that would be available without a prescription from a pharmacist. Although the CMEA2005 would appear to be a step in that direction, many within and outside of our profession consider it to have failed. In addition to pseudoephedrine, the FDA has also implemented requirements for the legal sale and use of drug products containing ephedrine and phenylpropanolamine.

When the nonprescription use of oral pseudoephedrine-containing products was changed to BTC availability, most manufacturers of these products reformulated them to remove pseudoephedrine and replace it with phenylephrine. Although phenylephrine is effective when administered intranasally and parenterally, its effectiveness as a nasal decongestant when administered orally has been debated at length. However, most health professionals were of the opinion that orally-administered phenylephrine is not effective when used in the recommended dosage, and that increasing the oral dosage would result in an unacceptable risk of adverse events. Nevertheless, the FDA permitted the pharmaceutical companies to make these formulations, and then incongruously compounded this error by permitting the companies to retain the original trade name for the new products with a different ingredient. For example, Sudafed, the best recognized trade name for single-ingredient oral OTC pseudoephedrine products, was changed to Sudafed PE when pseudoephedrine was replaced with phenylephrine. This strategy only serves the interests of the pharmaceutical companies who hope that consumers won't recognize or understand that a change has been made, and purchase the reformulated product. This marketing ploy is not only deceptive and insulting for consumers, but it is also confusing and potentially dangerous. Some consumers believe that Sudafed PE is Sudafed with an added ingredient that increases effectiveness. Some who have previously used Sudafed, conclude that Sudafed PE does not work as well at the recommended dosage, and increase the dosage and incur a greater risk of adverse events.

Questions regarding the effectiveness of oral phenylephrine have existed for many decades, but the drug has survived and remained on the market in spite of flawed old "studies," numerous reviews and challenges, more recent studies, and the opinions of most health professionals that it is not effective when used in the recommended dosage. When pseudoephedrine was switched from OTC to BTC status, and was replaced with phenylephrine in many OTC products, the use of phenylephrine markedly increased and accounted for retail sales of $1.8 billion in 2022, which is considered an underestimate.

Advisory Committee meeting

To its credit, the FDA convened a meeting of its Nonprescription Drugs Advisory Committee on September 11-12, 2023 to consider the efficacy of oral phenylephrine as a nasal decongestant. The scheduling of the meeting was for the purpose of reviewing the history, more recent studies and updated information regarding the efficacy of oral phenylephrine, and opinions of some FDA officials that its use should be considered again. The FDA provided Committee members with an 89-page Briefing Document that included the regulatory history of the products, summary results of older and more recent studies, and some preliminary thoughts of FDA reviewers. A phrase from an old song runs through my mind, "Second verse – same as the first."

This information was presented at the Advisory Committee meeting, as was detailed information provided by the Consumer Healthcare Products Association (CHPA) in its presentation, "Evidence Supporting the Efficacy of Oral Phenylephrine and its role in U.S. Healthcare." The CHPA member companies include those that market and promote the oral phenylephrine products. Those who enjoy fiction disguised as "evidence" should read the 94-page CHPA report that is accessible on the FDA website (www.fda.gov).

The agenda for the Advisory Committee meeting is established by the FDA and, toward the end of the 2-day meeting spent discussing the information provided by the FDA and other interested parties, members of the Committee were requested to vote on a single question identified by the FDA. As a random, radical idea, why not let the members of the Committee who are selected because of their expertise be involved in the determination of the agenda and the issues/questions/votes to be considered? The single FDA question to be voted on was:

> "Do the current scientific data that were presented support that the monograph dosage of orally administered phenylephrine is effective as a nasal decongestant?"
>
> If yes, discuss what data you consider supportive.
>
> If no, discuss what additional data, if any, are needed to assess phenylephrine pharmacokinetics or efficacy.

It can probably be assumed that the members of the Advisory Committee did not need a third day or even five more minutes to be ready to cast their votes. They voted UNANIMOUSLY "that the current (and presumably any previous [editor's speculation]) scientific data do not support the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant." Is it possible that the "science/evidence" has finally caught up with more than 60 years of experience, studies that did not provide evidence, reasoning, and common sense? I was interested in the topic for the meeting but did not attend or submit comments because my testimony at such previous meetings on other topics had been exercises in futility. I have to think that by late afternoon of September 12, members of the Advisory Committee had glazed eyes and were fatigued from reviewing complex and conflicting information, statistics, and graphs, and were experiencing nasal congestion as a placebo response and anxiety regarding how soon they would be able to return to their more meaningful responsibilities. However, the members of the Committee should be commended and appreciated for their expertise, service, and decisive and emphatic conclusion.

The media coverage of the meeting quickly disseminated the information that oral phenylephrine is safe but doesn't work. Some consumers raised valid question such as:

> Why is an ineffective medication on the market and still available?
>
> Why is phenylephrine in so many widely-promoted combination products and increasing their cost if it is not effective?
>
> Is it safe?
>
> Who makes these decisions?
>
> Who is looking out for us and protecting our health?

In rapid response mode, the FDA snapped into action and on September 14 issued a statement, "FDA clarifies results of recent advisory committee meeting on oral phenylephrine." The emphasis of the statement is, "Neither FDA nor the committee raised concerns about safety issues with use of oral phenylephrine at the recommended dose."

But wait – there's more! Does the FDA clarification statement suggest to some that oral phenylephrine is without risk even though it doesn't work? Is the warning that individuals should not take phenylephrine if they are being treated with a monoamine oxidase

inhibitor no longer applicable? Does the observation that no concerns about safety issues were made at the meeting mean that phenylephrine will not cause adverse events in anyone? The explanation for the statement that concerns about safety issues were not raised at the meeting is because the FDA constructed the agenda that did not include any consideration of safety. The Advisory Committee members were not asked to address safety issues and would probably have been ruled to be out of order if they did.

It would appear that another clarification statement is now necessary! I will suggest a title and a beginning of the statement, and let the FDA take it from there.

FDA clarifies previous clarification about phenylephrine

"In our previous clarification statement of September 14 about phenylephrine, we didn't really mean to include a comment that some may interpret that the drug is safe for everyone, because it isn't actually safe for everyone."……

There are many very intelligent and dedicated employees at the FDA, some of whom I know personally and hold in high regard. I have to think that the decision-makers/leaders at the FDA are also very capable. So why is the FDA so dysfunctional? It is not just the perennial decongestant debacle in which the dysfunction is evident, but also myriad other issues such as:

1. the approval of aducanumab (Aduhelm) for Alzheimer's disease after another advisory committee was almost unanimous in its recommendation that it not be approved;

2. its deception in trying to assure the public that all generic products are of the same composition (of active ingredient[s]) and quality as the original trade-name products at a time when the marketplace is flooded with counterfeit products, as well as "generic" products from certain fraudulent companies (particularly in India and China) that are often *not* equivalent, are contaminated, and/or dangerous;

3. its multiple failures during the COVID-19 pandemic including a) the approval and promotion of vaccines for which neither efficacy nor safety were sufficiently demonstrated; b) its issuance of certain statements (often in conjunction with the CDC, NIH, and other government officials) that were not supported by science, evidence, experience, or reason; c) its lack of transparency by refusing to release detailed information regarding efficacy and safety study results of vaccines and medications that would be of value for health professionals and the public, and essentially ignoring the many thousands of reports of vaccine events entered in the Vaccine Adverse Event Reporting System; and

4. its mismanagement, with the DEA, of the opioid crisis in a manner that has resulted in patients with conditions characterized by severe, persistent pain that requires management with potent analgesics in high doses, often not being able to obtain needed medications on a timely basis.

Notwithstanding the above situations, as well as others, the FDA has a feature on its website titled "Rumor Control" that includes the following statements:

> "Learn and share FDA facts to help stop the spread of misinformation."
>
> "Find the Truth – Get the latest fact checks and help stop the spread of false rumors."
>
> "The growing spread of rumors, misinformation and disinformation about science, medicine, and the FDA, is putting patients and consumers at risk. We're here to provide the facts."
>
> "Don't be misled by misinformation."

It is my opinion that it is the FDA that has been the source of more misinformation than has come from any other organization or individual, and that it is the

FDA that is putting the largest number of patients, consumers, and health professionals at risk, because it is the agency that is expected to have the expertise and authority in which the public and health professionals should be able to have full confidence.

Who makes the decisions?

The documents which the FDA provides to all advisory committees include the following statement:

> "The Commissioner has sole discretion concerning action to be taken and policy to be expressed on any matter considered by an advisory committee."

The Commissioner has awesome authority, so why have so many Commissioners in recent years failed in their responsibilities and decisions? I do not doubt for a minute that they are very intelligent individuals who were very accomplished in their previous responsibilities. Therefore, I must conclude that the Commissioners are also victims, like the public, of the regulatory bureaucracy, and the politics, power, and influence of individuals and organizations which have even greater authority and resources. Is it possible to lead, let alone effectively manage, in such an environment?

With regard to oral phenylephrine, I respectfully submit the following recommendations for consideration by the present Commissioner:

1. Require that the companies that make and promote oral phenylephrine-containing products cease making and distributing them by December 31 (*this year* – not 2024 or later). I acknowledge that this would be a bold and unprecedented action, but such boldness is necessary – the *status quo* and long delays are unacceptable and continue to put the public health and safety at risk;

2. Reorganize the structure, responsibilities, and personnel of the FDA in a manner that results in more independent, effective, and efficient decision-making on a timely basis.

3. If political pressure and power prevent you from doing what is best for the public interest – Resign! You will be a HERO to those who are the most important – the public – and you can return to your previous and more-fulfilling life and responsibilities.

PHARMACISTS to the rescue!

Independent pharmacists and pharmacists in corporate retail settings have the opportunity to provide leadership in resolving the decongestant debacle with an immediacy that is not possible for the FDA.

1. Remove all oral phenylephrine-containing products from the shelves and announce that you are discontinuing the sale of products containing an ingredient that is not effective. Return the products to the companies from which they were purchased and insist on a full refund.

2. Choose selected single-ingredient and combination products in which you have the most confidence and which will comprise your Pharmacist's Choice "formulary."

3. Promote your expertise and services with a message such as:
   "Please speak with our pharmacist for a personal assessment and recommendations for treating cold, cough, sinus, and allergy symptoms."

4. Not all pharmacies will stop selling oral phenylephrine-containing products. Consider adding the following to the message above:
   "Those who wish to use a product that includes an ingredient that is not effective may find it at (insert the name of your least favorite corporate retail predator/competitor).

5. Seize the day!

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CAPTURED! – Heroes and Non-heroes

A convicted murderer escaped from the Chester County Prison (approximately 30 miles outside of Philadelphia) on August 31. The resulting manhunt that received international media coverage continued over the last two weeks until the 5-foot, 120-pound fugitive was captured on September 13. More than 500 heavily-armed local, state, and federal police and others in law enforcement, with the support of police dogs, police on horses, drones, helicopters, thermal imagery and other sophisticated technology, and local residents, participated in the manhunt. Residents in the immediate community and for miles into the extended community lived in fear that intensified each day that the fugitive eluded capture. Schools and many businesses closed, and residents and travelers encountered numerous roadblocks and sometimes vehicle searches.

HEROES

There are numerous heroes in this story including:

1. The hundreds of police and others who experienced personal risk and challenges as they persistently navigated through difficult terrain and severe thunderstorms in their commitment to protect the residents of a widening geographical area.

2. The many thousands of residents in the communities, many of whom lived in fear of the escaped murderer but who provided helpful information, support, and encouragement for the on-ground law enforcement personnel.

3. The police dog. In the early morning of September 13, with the support of a helicopter and thermal imagery, more than 20 police came to an area in which it was thought the fugitive was hiding, although he had not been actually sighted. The police dog was released, quickly located and subdued the fugitive, and prevented his use of a rifle he had stolen.

4. The residents/taxpayers of Pennsylvania who will ultimately pay millions of dollars via their taxes to cover the cost of the manhunt for the murderer who should not have been able to escape from the prison.

NON-HEROES

There are also individuals who, at the least, must be questioned about their role, or silence, about the recent events, including:

1. The officials/administrators of the Chester County Prison, and the local and state government officials to whom they are responsible. Several months ago, another prisoner escaped from the Chester County Prison, but he was quickly apprehended. Because of the failure of those in authority to immediately take action to restore and strengthen security at the facility, the convicted murdered escaped in the same manner.

   It has been reported that the prison tower guard on duty at the time of the escape two weeks ago has been fired. However, it has also been suggested that the escape of the fugitive occurred so quickly that it may not have been observed. A question has been raised as to whether this unidentified prison guard is a scapegoat, but it has been explained that he

violated policy because he had a cell phone in the prison tower, the use of which would be a distraction. I have not heard even a question about whether others with greater responsibility will also be fired.

2. The Pennsylvania State Police official who developed the strategy for and directed the manhunt, and presided at press conferences in the command center. His early comments touting the strategy and his assurances that the fugitive would be quickly captured gave way to myriad explanations/excuses as to why he had not been and how he had been able to escape through a "perimeter" of law enforcement officials and blockades that were initially suggested to be impenetrable. His subsequent comments and responses to questions included statements that nothing had gone wrong concerning planning and conducting the manhunt, and that the strategy was appropriate and had been carried out as planned.

   This State Police official was adamant in declaring that anyone who was found to aid the fugitive would be prosecuted to the fullest extent of the law. Does this include the individuals whose failures permitted the escape in the first place? We can only hope that the unsuspecting and trusting resident outside of "the perimeter" who left the keys in his unlocked truck that the fugitive stole to escape the immediate area, will not be prosecuted.

3. The Governor of Pennsylvania. To his great credit, the Governor provided exceptional leadership in the recent repair of the section of interstate route 95 that had collapsed following a fire. Hundreds of thousands of travelers were able to resume use of I-95 much sooner than most thought possible. However, the Governor was essentially silent and invisible regarding the escape of the murderer and the manhunt – until he was captured. Has his silence been because this situation reflects negatively on the Commonwealth of Pennsylvania and him? The press conference regarding the capture of the fugitive was initially scheduled for 9 am on September 13, but it was delayed until about 10 am. A question has been raised as to whether the delay occurred to provide time for the Governor to arrive and participate in announcing the great news of the capture and providing accolades for many. The Governor also attempted to make a joke about the Philadelphia Eagles football jersey the fugitive was wearing at the time he was captured. The media has essentially ignored this attempt at humor at an event at which it was not appropriate.

Irony and additional questions

It is ironic that the heroes of this experience are anonymous, with the exception of the police dog which was identified later in the day as Yoda. However, two of the non-heroes are very well known. There are many additional questions that should still be asked, but there have been no assurances that will be done.

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