The Pharmacist Activist

Volume 17, No. 3 • March 2022

"The Lord is righteous in all his ways and loving toward all he has made. The Lord is near to all who call on him, to all who call on him in truth." Psalm 145: 17-18

Editorial

COVID-19 Vaccine Follies – Are There Really Any "Experts"?

I have received the first two doses of the Moderna COVID-19 vaccine and also the Moderna booster immunization. I have been an advocate for widespread immunization against COVID-19 and never had a question that I would be among those receiving the immunization on a timely basis. However, based on what I have learned from closely following/studying the risks of the pandemic, as well as the benefits and limitations of the vaccines, I am holding off in making a decision as to whether I will receive the second booster dose (for a total of 4 doses) that some "experts" are now recommending. My hesitation is based, in part, on what are now recognized as limitations in the protection of the vaccines (e.g., against newer variants of the virus such as omicron) and the relatively brief period of time in which protection against the virus is provided. The latter observation has some anticipating a need for relatively frequent booster shots until the risks from the virus have declined to a still-to-be defined acceptable level.

Many American adults have decided to not be immunized against COVID-19, and they have been accused by some as being conspiracy theorists and selfish. In my opinion, the primary reason for which individuals have not been immunized is because they cannot determine whose advice can be trusted. "Follow the science" has been such a widely used admonition and often used to support advice that is not based on science, that the credibility of the term has declined. Advice to "trust the experts" has similar vulnerabilities as the recommendations of "experts" with seemingly similar expertise and credentials are at the extremes of the spectrum of opinions and contradictory. A recent comic strip (Scott Adams) depicting a conversation of Dilbert with a colleague captures the dilemma:

Colleague: "You should follow the advice of experts."
Dilbert: "What if the experts disagree?"
Colleague: "Side with the majority."
Dilbert: "Is that how science works?"
Colleague: "Well, no. You also have to do your own research to know which experts are right."
Dilbert: "If I knew which experts were right, wouldn't that make me smarter than the experts?"
Colleague: "Doing my own research works for me, so you can always come and ask me who is right."
Dilbert: "How would I know you are right?"
Colleague: "Because I do my own research."
Dilbert: "Maybe you can teach the experts how to do that."

Given the complexity of viruses, immune function, and the COVID-19 pandemic, perhaps it is not surprising that the opinions of those who have the greatest expertise in these areas differ so widely. Most of these individuals have provided their honest assessments and recommendations; however, the statements of some are financially and/or politically motivated. One of the strongest recent assessments is that a fourth dose (second booster) of the vaccine "is necessary," notwithstanding the fact that no FDA,

Contents

"CVS Ousts Executives After Probe"........ Page 2
New Drug Review: Atogepant (Qulipta – AbbVie)........ Page 3

CDC, NIH, or other government authority has made this recommendation at this time. The individual who made this declaration is the CEO of Pfizer, whose company will receive a windfall of billions more dollars. This is a blatant and highly inappropriate promotion of an off-label use use of the vaccine, and must be viewed as an attempt to influence decisions rather than the opinion of an expert with no vested interests. If Pfizer sales representatives were to make this recommendation, they would be terminated by the company, and there would be federal charges against the company. The FDA must be shocked to the point of being silent while it determines what action it can take against a CEO.

Most healthcare journalists are very knowledgeable regarding the topics on which they report. However, many in the media who may have little knowledge of science and would not be able to accurately describe the roles and differences of antigens and antibodies, have anointed themselves as authorities in stating/promoting the opinions of others with political or other affiliations with which they agree. At the same time, some criticize, insult, and demean those who hold differing views, by characterizing them as conspiracy theorists, science-deniers, and as promoting recommendations that have not been proven. Often, those being criticized have far more knowledge about COVID-19 and related issues than the media who are denouncing their views.

The widespread availability and use of vaccines have been claimed to prevent many serious complications and deaths from COVID-19, and some have even attached estimates to these claims. However, this ignores the impossibility of trying to count/quantify events that do not occur. This reality is well known in the profession of pharmacy with respect to our decades-long efforts to convince the public and payers of the value of our services and interventions that prevent a large number of adverse events, hospitalizations, and deaths. However, we can't count things that didn't happen, and our success in convincing others of the life-saving value of our responsibilities has been limited.

The awareness of adverse events and other risks of the COVID-19 vaccines continues to evolve. There have been tens of thousands of reports of such events submitted to the Vaccine Adverse Event Reporting System (VAERS), but individual reports are not verified and a cause-and-effect relationship with the use of a vaccine can't be documented or assumed. However, the increasing number of reports of problems such as Guillain-Barre syndrome, myelitis, myocarditis, hearing loss/tinnitus, multi-system inflammatory syndrome, and other events warrant close monitoring and thorough study. I continue to believe that the value of the COVID-19 vaccines greatly exceeds the risks, but I have growing concerns regarding what is still unknown about the risks.

Very few, even among the "experts," knew about COVID-19 prior to the pandemic. New strategies (e.g., involving messenger RNA) have been used in the production and use of certain COVID-19 vaccines with which there was very limited prior knowledge and experience. The vaccines were developed and evaluated in a much shorter period of time than typically would have been considered necessary. Clinical trials were abbreviated, and information regarding the extent and duration of the protection provided by the vaccines is still very limited. No information is yet available on the long-term safety of the vaccines. So based on essentially two years of observation and experience, can anyone truly be considered an "expert" regarding COVID-19 and the vaccines and treatment?

The answer to this question is "Yes," because the prior training, experience, and expertise of certain individuals, supplemented with the knowledge acquired in the last two years and thoughtful reasoning qualifies them as experts. There are individuals whose observations and recommendations I find very credible and have a high level of confidence. However, there are also some presumed "experts" who I do not trust. Based on my extensive study of the topic, and even publishing commentaries, I am now declaring myself an expert. Trust me!.

Daniel A. Hussar
danandsue3@verizon.net

"CVS Ousts Executives After Probe"

As if CVS pharmacists and pharmacy technicians did not already experience enough anxiety, panic attacks, and other mental health challenges from the management-imposed metrics and policies that result in understaffed, stressful, and error-prone workplaces, the occurrence and mishandling of sexual harassment complaints has now become public. The title for this commentary is the one used for a recent *Wall Street Journal* story* (WSJ; Sharon Terlep, Suzanne Kapner; March 12-13, 2022; page B3).

Based on allegations and an internal investigation, CVS dismissed a regional manager who oversaw hundreds of stores, the executive who supervised him, a human-resources executive, and others. In a communication to staff, Karen Lynch, the CEO of CVS stated: "I want to be crystal clear: this company does not tolerate harassment or hostile, abusive or discriminatory behaviors of any kind from any employee – regardless of position…We also will not tolerate inaction from leaders who are responsible for escalating concerns or allegations raised by our colleagues." The communication continues in noting that the company would improve its internal reporting and investigation processes, and had created a confidential communications channel to bring concerns to the attention of senior leaders.

(Continued on Page 4)

New Drug Review

Migraine

Atogepant (Qulipta – AbbVie)

Description:
A calcitonin gene-related peptide (CGRP) receptor antagonist.

Indication:
Administered orally for the preventive treatment of episodic migraine in adults.

New Drug Comparison Rating (NDCR) = 3
(no or minor advantages/disadvantages) in a scale of 1 to 5 with 5 being the highest rating

Comparable drugs:
Rimegepant (Nurtec ODT); (ubrogepant (Ubrelvy) is also an orally-administered CGRP receptor antagonist that is only indicated for the acute treatment of migraine).

Advantages:
- May be less likely to cause hypersensitivity reactions (which are identified as a warning in the labeling for rimegepant);
- May be used in an adjusted dosage with interacting medications (whereas the concomitant use of rimegepant with a strong CYP3A4 inhibitor, strong and moderate CYP3A4 inducers, or inhibitors of P-glycoprotein or breast cancer resistance protein should be avoided).

Disadvantages:
- Labeled indications are more limited (rimegepant is also indicated for the acute treatment of migraine);
- May be more likely to cause fatigue.

Recommended dosage:
10 mg, 30 mg, or 60 mg once a day - dosage modifications:
- 10 mg once a day in patients also being treated with a strong CYP3A4 inhibitor, or in patients with severe renal impairment/end-stage renal disease;
- 10 mg or 30 mg once a day in patients also being treated with an organic anion transporting polypeptide (OATP) inhibitor;
- 30 mg or 60 mg once a day in patients also being treated with a strong or moderate CYP3A4 inducer

Products:
Tablets – 10 mg, 30 mg, 60 mg.

Contraindications/most important risks:
- Pregnancy (may cause adverse developmental effects based on animal studies);
- Hepatic impairment (should be avoided in patients with severe hepatic impairment);
- Renal impairment (should be used in a lower dosage in severe renal impairment and end-stage renal disease);
- Interactions: Strong CYP3A4 inhibitors; increase activity of atogepant which should be used in a lower dosage;
  Strong and moderate CYP3A4 inducers; decrease activity of atogepant which should be used in a higher dosage;
  OATP inhibitors; increase activity of atogepant which should be used in a lower dosage.

Most common adverse events:
Nausea (6%), constipation (6%); fatigue/somnolence (4%).

Comments:
Atogepant is the third CGRP antagonist for oral administration in the management of migraine, joining rimegepant and ubrogepant. However, the labeled indications for the three agents vary, with ubrogepant indicated for the acute treatment of migraine, atogepant for the preventive treatment of episodic migraine, and rimegepant for both but in different dosage regimens. Four other CGRP antagonists are administered parenterally for the preventive treatment of episodic migraine and chronic migraine, and these agents include erenumab (Aimovig), fremanezumab (Ajovy), galcanezumab (Emgality), and eptinezumab (Vyepti). Galcanezumab also has a labeled indication for the treatment of episodic cluster headache.

Atogepant was evaluated in two 12-week placebo-controlled studies in patients with episodic migraine (4-14 monthly migraine days [MMD]), in which the primary efficacy endpoint was the change in baseline in mean MMD (7.5 – 7.9 MMD). Dosages of 10 mg, 30 mg, and 60 mg daily of atogepant reduced migraine frequency with the difference from placebo being a reduction of approximately 1 MMD.

Daniel A. Hussar

Visit www.pharmacistactivist.com for a FREE subscription

The statements of the CVS CEO are commendable and seemingly unequivocal. However, the situations that occurred and her comments raise additional questions:

1. Would this situation have become publicly known if it were not for the discovery of WSJ reporters, or would it have been buried in confidential CVS corporate files? My long-term observations have been that CVS will take any action necessary to suppress information that could result in negative publicity.

2. Why have the individuals who have been terminated not been identified? In addition to CVS management, their identities are known to the WSJ reporters who reached out to them but did not receive a response or they refused to comment?

3. Although some will consider termination from an executive position to be a strong action, have these experiences and individuals been reported to law enforcement or regulatory agencies, or to organizations that accredit components of CVS operations? Might it be expected that the terminated individuals may be hired in executive positions at companies such as Walgreens, Walmart, or Rite Aid who may be impressed with their executive responsibilities at CVS but not be aware of the reasons for their departures?

4. What took so long for these experiences to be discovered by top management and for action to be taken? Although a thorough investigation takes time, there have been rumors and allegations on social media for many months from CVS employees who are familiar with these experiences but can't report them for fear of retaliation. Could the high-level executives of CVS have been completely ignorant/oblivious to situations that were apparently known to numerous employees?

5. Are the situations reported in the WSJ story just the "tip of the iceberg?" In the short period of time since the story was published there have been social media posts from CVS employees about other experiences that seem similar or even worse.

6. Although the word "harassment" is commonly applied to inappropriate sexual comments or behaviors, it is also applicable to other situations such as intolerable and dangerous workplace conditions that are widely known. Are these not abusive behaviors that are among those that the CVS CEO indicates will not be tolerated? Now that a confidential channel of communication has been established for employees to bring concerns to CVS senior leaders, every CVS employee who is concerned that working conditions increase the risk of harmful and even fatal errors for customers, or jeopardize their own personal mental and physical health should document these experiences and communicate them through the confidential channel that has been established.

7. Will anything actually change at CVS?

Pharmacist Steve Ariens often brings to my attention pharmacy-related experiences of which I may be unaware. Last fall he shared with me the tragic news of the death of pharmacist Ashleigh Anderson who collapsed and died in the CVS store in which she worked in Indiana. My tribute to and commentary regarding Ashleigh is in the November, 2021 issue of *The Pharmacist Activist*. Steve just forwarded to me a photo of a large billboard sign at the Scottsburg, Indiana northbound exit of I-65. The billboard includes an excellent photo of Ashleigh next to a heart that includes her first name and the dates of her birth and death. It also includes the designation #SHEWAITED, and the important message, "Your job can wait. Your heart can't." I highly commend and thank those who designed and posted this fine tribute to Ashleigh.

Daniel A. Hussar
danandsue3@verizon.net

Free Subscription
Go to www.pharmacistactivist.com
to sign-up for a FREE subscription.
The Pharmacist Activist will be provided FREE via e-mail to interested pharmacists and pharmacy students who request a complimentary subscription by signing-up online at:
www.pharmacistactivist.com

Author/Editor/Publisher – Daniel A. Hussar, Ph.D.
Dean Emeritus and Remington Professor Emeritus at Philadelphia College of Pharmacy
Assistant Editor – Suzanne F. Hussar, B.Sc. (Pharmacy)

The Pharmacist Activist, 1 Boulder Creek Lane, Newtown Square, PA 19073
E-mail: info@pharmacistactivist.com

Distribution/Design Services provided by Jeff Zajac