The Pharmacist Activist

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"They exchanged the truth of God for a lie, and worshiped and served created things rather than the Creator – who is forever praised." Romans 1:25

Editorial

Walgreens Should be Removed from Vaccine Programs!

"Walgreens Not Following U.S. Guidance on Pfizer Vaccine Spacing" is the stunning title of a recent story in *The New York Times* (April 5, 2021; Rebecca Robbins). The story includes the following statements:

"Walgreens has inoculated hundreds of thousands of Americans against COVID-19 this year using the vaccine developed by Pfizer and Germany's BioNTech. But the pharmacy chain has not been following guidance from federal health officials about the timing of second doses."

"People are supposed to get two doses, three weeks apart. Walgreens, however, separated them by four weeks because that made it faster and simpler for the company to schedule appointments."

"But Walgreens's decision, which it didn't publicly announce, confused some customers and caught the attention of federal health officials….a spokeswoman for the C.D.C. said the agency had asked Walgreens to stop using a longer-than-recommended period between doses."

"The company's vaccine-scheduling system by default schedules all second doses four weeks after the first. Doses of Moderna's vaccine, which Walgreens is also administering, are supposed to be spaced four weeks apart. Using the same gap for both vaccines was 'the easiest way to stand up the process based on our capabilities at the time,' Dr. Kevin Ban, Walgreens' chief medical officer, said in an interview."

"Now Walgreens is changing its system."

"The vaccination program is a business opportunity for Walgreens, which is bringing in revenue from the vaccine administration fees paid by government and private payers as well as from purchases made by shoppers coming in for vaccines."

"Asked about Walgreens' scheduling, …a spokesman for Pfizer said the safety and efficacy of the company's vaccine had not been evaluated on dosing schedules different from the three-week gap tested in clinical trial volunteers."

"Walgreens' decision to not adhere to the C.D.C.'s guidance on dose spacing for Pfizer's shot left some customers confused." One individual "who got her first Pfizer shot late last month has been trying, to no avail, to reach a Walgreens representative to reschedule her second-dose appointment for a week sooner."

Contents

Arrogance and greed

In my opinion, there will NOT be any clinically important difference in the protection provided by the vaccine whether the two doses are administered at 3- or 4-week intervals. However, Walgreens does NOT have the authority to change the dosage regimen. "Chaos" is not too strong a term to characterize the confusion and argumentative debate about the transmissibility of COVID-19, closing of schools and businesses, the effectiveness and safety of vaccines, vaccine distribution, etc. Walgreens' action only adds to the confusion and chaos!

Walgreens' action sends the following messages:

"The science and the clinical trial data can be ignored."

"The FDA-approved dosage regimen and CDC guidance can be ignored."

"We will decide on 'the easiest way' for us to give the vaccine for our convenience, metrics, and revenue."

The statement of the Walgreens medical officer that it chose "the easiest way… based on our capabilities at the time" is ludicrous and must be rejected. If Walgreens does not have the capability to schedule consumers at different time intervals, is it capable of storing and handling the vaccines in the proper manner, or administering the correct dose? The Walgreens self-serving action is based on its greed and arrogance to give more vaccines to more people faster to acquire greater profits.

Remaining questions

What is the FDA's response to Walgreens' action?

What actions have state boards of pharmacy taken in response to Walgreens' action?

Does Walgreens' action violate professional ethics?

How do pharmacy's professional associations view this action?

Are there other vaccines or medications for which Walgreens has determined "the easiest way" to adjust dosages and administer them (e.g., vaccines, antibiotics, cancer chemotherapy)?

Or is there silence?

The last question is the only one for which there appears to be an answer, so I will break the silence! Walgreens should be removed as a participant in vaccine immunization programs!

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Is Your College of Pharmacy/Alma Mater Holding an In-person Commencement?

The COVID-19 pandemic has been cause for many cancelations and closures, and restrictions on many other activities. Fortunately, we have learned more about the necessary precautions, vaccines have been developed at an unprecedented pace, and an increasingly larger fraction of the population most at risk have been immunized.

As licensed pharmacists, the vast majority of us had the opportunity to celebrate our accomplishments and graduation with family, friends, and faculty. The Class of 2021 should be provided that same opportunity! Young people are at extremely low risk of experiencing active COVID-19 infection. Older individuals such as grandparents, faculty, and those with risk factors can opt out if they choose to not attend a commencement ceremony or subsequent celebrations. It is ironic that some Pharmacy graduates will be working full-time at a practice site at which they are exposed to risk of COVID-19 on the day following their virtual graduation.

Some colleges of pharmacy have stopped in-person instruction and other college activities with the exception of certain laboratories and experiences considered essential. Now, however, states and local jurisdictions are lifting restrictions and limits on the size of gatherings – just in time to enable celebrations of memorable events such as commencement.

Regrettably, some university and college of pharmacy administrators appear to have more of an interest in keeping activities closed down, than in identifying ways to recognize the accomplishments of their students and graduates in person. The Class of 2021 should not be denied the opportunity of a commencement that has been so important and memorable for us. If your alma mater is not planning an in-person commencement, we should support our new graduates and colleagues by insisting they have that opportunity.

Daniel A. Hussar

New Drug Review

Insomnia

Lemborexant (Dayvigo – Eisai)

Description:
An orexin receptor antagonist.

Indication:
Administered orally for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

New Drug Comparison Rating (NDCR) = 3
(in a scale of 1 to 5 with 5 being the highest rating)

Comparable drugs:
Suvorexant (Belsomra).

Advantages:
- Has been demonstrated to be more effective than zolpidem extended-release 6.25 mg.

Disadvantages:
- Has not been directly compared with suvorexant in clinical studies;
- Concurrent use with strong or moderate CYP3A inhibitors or strong or moderate CYP3A inducers should be avoided (whereas suvorexant may be used concurrently with CYP3A inducers, and in a low dosage with moderate CYP3A inhibitors).

Recommended dosage:
5 mg immediately before going to bed, with at least 7 hours remaining before the planned time of awakening;
- Time to sleep onset may be delayed if taken with or soon after a meal;
- No more than one dose should be taken each night;
- Dosage may be increased to the maximum recommended dose of 10 mg each night;
- Maximum recommended dose is 5 mg at bedtime in patients with moderate hepatic impairment or who are being treated with a weak CYP3A inhibitor.

Products:
Film-coated tablets – 5 mg, 10 mg.

Contraindications/most important risks:
- CNS depressant effects and daytime impairment; consumption of alcoholic beverages should be avoided; patients treated with the 10 mg dose should be advised against next-day driving and other activities requiring full alertness;
- Abuse potential: (Schedule IV);
- Sleep paralysis/hallucinations;
- Cataplexy-like symptoms (e.g., periods of leg weakness);
- Complex sleep behaviors (e.g., sleep-walking, sleep driving);
- Worsening of depression/suicidal ideation;
- Pregnancy: women should be registered in the Dayvigo pregnancy registry (1-888-274-2378);
- Hepatic impairment: use should be avoided in patients with severe hepatic impairment;
- Interactions: use should be avoided in patients treated with strong or moderate CYP3A inhibitors or strong or moderate CYP3A inducers;
- May decrease the activity of CYP2D6 substrates (e.g., bupropion, methadone).

Most common adverse events
(with doses of 5 mg and 10 mg, respectively):
Somnolence (7%, 10%), headache (6%, 5%), nightmares/abnormal dreams (1%, 2%).

Comments:
The orexins are naturally occurring neuropeptides that act in a signaling mechanism as a central promoter of wakefulness. Lemborexant is the second orexin receptor antagonist that blocks the binding of the orexins to their receptors, and is thought to suppress the wake drive. It was evaluated in two clinical trials, one of which was placebo- and active-controlled (zolpidem extended release 6.25 mg). Both 5 mg and 10 mg doses of lemborexant demonstrated statistically significant superiority compared with placebo and zolpidem extended-release 6.25 mg in reducing the time to sleep onset, as well as improvement in sleep efficiency (percentage of time asleep compared with time in bed), and the time awake after sleep onset.

Daniel A. Hussar

Many Pharmacy Associations, Colleges of Pharmacy, and Pharmaceutical Companies Use PBMs that are Destroying Our Profession!

Community pharmacists identify prescription benefit programs administered by most PBMs and health insurance companies as the greatest threat to their ability to practice professionally in serving their patients. Independent pharmacy owners identify these programs as the most important threat to their financial survival, with the result that so many independent pharmacies and smaller pharmacy chains have been sold or forced to close. Even a large, successful national retail organization like Target failed at being able to operate pharmacies profitably, with the result that it sold their pharmacies to CVS. The prescription benefit programs are non-negotiable, provide inadequate compensation for services, mandate or provide financial incentives for patients to use mail-order or chain pharmacies they own, and/or charge egregious DIR fees. CVS Caremark, Express Scripts, and Optum are the largest PBMs and control the terms and compensation for the programs in which a large majority of prescriptions are dispensed in the United States. The owners and administrators of these programs are depriving patients of important counseling and other professional services, are making it difficult if not impossible for local pharmacies to financially survive, and are destroying the profession of pharmacy.

The enablers

Government agencies, corporations and other employers, and unions are, perhaps, unaware of the consequences of the programs, terms, and action of many PBMs. However, pharmacy associations, colleges of pharmacy, and pharmaceutical companies are well aware of the information provided above. Yet many of these organizations use and subsidize these PBMs in providing prescription benefit programs for their employees. When challenged regarding their support for the PBMs that are destroying the profession for which they claim to be advocates, they often respond by saying they have few choices for providing prescription "benefits," and it is difficult to identify prescription programs that will provide adequate services for employees and adequate compensation for pharmacists. These responses must be rejected! There are other options, but these organizations don't look for them and their constituencies do not challenge them to do so.

Why should pharmacists pay dues to be members of pharmacy organizations that use/support PBMs that are destroying our profession?

Why should pharmacists respond to appeals for alumni contributions from their colleges of pharmacy that use/support the PBMs that are forcing some of their graduates to close their pharmacies?

How many pharmacists know whether their alma mater or associations in which they are members are using a PBM that is undermining our profession?

Why don't most pharmacists, even pharmacist faculty or employees of pharmacy organizations, ask these questions?

An obituary

A group of independent pharmacists and like-minded individuals invested their own funds in establishing IndyHealth, a prescription insurance/benefit program that supported the professional role of pharmacists and comprehensive services for patients, and which provided fair compensation for pharmacists. IndyHealth had initial authority to provide Medicare Part D prescription plans in five states – Arkansas, Georgia, Illinois, Pennsylvania, and West Virginia – which became effective on January 1, 2021. My wife and I signed up as participants in this program in Pennsylvania. In less than three months, we were informed that this program would end on March 23, 2021 and that we would be temporarily enrolled in another program. IndyHealth had failed!

I continue to highly respect and commend the pharmacists who had the courage and made the investment to challenge what they recognized to be formidable competition. Although IndyHealth failed and succumbed to the size, strength, influence, and anticompetitive practices of the giant PBMs, these pharmacists at least tried to make a positive difference, whereas most in our profession have done nothing in response to these concerns.

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