The Pharmacist Activist

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"Have I not commanded you? Be strong and courageous; do not be terrified; do not be discouraged, for the Lord your God will be with you wherever you go." Joshua 1:9

Editorial

# Pharmacy at the Supreme Court

The largest pharmacy benefit managers (PBMs) – CVS/Caremark, Express Scripts, and Optum – have caused incalculable financial and collateral damage to community pharmacies, the profession of pharmacy, and the consumers whose prescription "benefit" plans they administer. Numerous previous editorials in *The Pharmacist Activist* have addressed these concerns. It is not an overstatement to warn that their egregious and destructive actions jeopardize the future of the profession of pharmacy – and this warning applies to the ENTIRE profession of pharmacy, not just community pharmacy!

Challenges to the PBMs from pharmacy organizations and individual pharmacists have been of very limited effectiveness. Our profession is losing the battle and is in a steep decline. Fortunately, there is a ray of hope that can be an important step on a forward path. However, a large majority of pharmacists, as well as a number of pharmacy organizations, are not aware of the specifics of the "ray of hope" to which I refer.

## October 6

On October 6, the Supreme Court of the United States (SCOTUS) will hear oral arguments (delayed and via conference call because of COVID-19 restrictions) in the case designated *Rutledge v. Pharmaceutical Care Management Association* (PCMA), the organization that represents PBMs. The journey to SCOTUS has taken five years from the time that legislation was approved in Arkansas that would require PBMs to increase their compensation to pharmacies for many prescriptions that were being dispensed at a financial loss, thereby jeopardizing the continued operation of the pharmacies. PCMA challenged the Arkansas law in the District Court and the judge's ruling supported one part of PCMA's argument (that the law was preempted by the Employee Retirement Income Security Act [ERISA]), but rejected another (that the law was preempted by Medicare Part D). PCMA appealed the District Court ruling that the Arkansas law was not preempted by Medicare Part D to the Circuit Court of Appeals. The Circuit Court reversed the District Court's ruling with respect to Medicare Part D, thereby supporting PCMA's challenge and striking down the Arkansas law. However, Mark Riley, Scott Pace, John Vinson, and colleagues with the Arkansas Pharmacists Association (APA) were not willing to accept defeat! Nor was Leslie Rutledge, the Attorney General of the state of Arkansas. With strong support from Doug Hoey and colleagues with the National Community Pharmacists Association (NCPA), Attorney General Rutledge appealed the Circuit Court's decision to the Supreme Court. This appeal received strong support from the U.S. Solicitor General who opined that the Circuit Court decision was not correct and recommended that the case be heard by SCOTUS.

In a typical year, SCOTUS agrees to consider only about 1% of the petitions to review lower court decisions that it receives. On January 10, 2020, SCOTUS announced that it would hear arguments in the *Rutledge v. PCMA* case, an action which has

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monumental importance for the profession of pharmacy, and represents the first time that the policies and practices of the PBMs have been challenged and heard at this level. The date of April 27, 2020 was initially announced as the time when SCOTUS would hear oral arguments, but, because of the impact of COVID-19, the Court will hear oral arguments by telephone conference on October 6, 2020. In addition to APA and NCPA, the American Pharmacists Association, the National Alliance of State Pharmacy Associations, and almost all of the state pharmacy associations have submitted an amicus curiae brief in support of Attorney General Rutledge's appeal to permit the state of Arkansas to regulate PBMs. Most of the rest of the profession of pharmacy (e.g., colleges of pharmacy, health-system pharmacists), as well as pharmaceutical companies, all of whom are affected at least indirectly by the outcome of this litigation, have been relatively silent. However, questions regarding their lack of involvement (interest?) are beyond the scope of this editorial.

## National implications

Although the appeal that SCOTUS will consider has been filed on behalf of the state of Arkansas, the decision to be made will have important national implications as pharmacy organizations and legislators in many states have previously challenged PBM inequitable and coercive programs and practices, but with little success. For example, in Pennsylvania, the state Auditor General identified major concerns with the PBM programs and their very negative impact on pharmacies and access of residents of the state to pharmacy services, but was unable to learn the financial terms for even the government-funded prescription programs that are administered by the largest PBMs under the cover of secret agreements.

There are no federal laws that are applicable to the compensation provided by PBMs to the pharmacies providing prescriptions to members of the PBM plans. Therefore, laws that states develop to address this issue challenge what the PBMs have claimed as their exclusive right to determine levels of compensation. The basic question to be addressed by SCOTUS is whether the Circuit Court made an error in ruling that the Arkansas law was preempted by the federal ERISA law. Its ruling will affect whether Arkansas can enact a law that addresses inadequate compensation to pharmacies in many PBM-administered prescription plans, or whether PBMs will be able to continue unimpeded in determining the compensation in these plans. The importance of this matter is reflected in the SCOTUS decision to hear the arguments in the appeal of the Circuit Court decision, and the PCMA appeal of the District Court ruling which partly, but not entirely, supported PCMA's position.

## Moving forward

I believe that the Arkansas appeal to SCOTUS is a strong one, and am optimistic that its ruling will favor Arkansas and the profession of pharmacy. However, nothing can be assumed and I have learned to never underestimate the influence of the PBMs. We have moved past the stages of the process in which the wealth and lobbying of the PBMs can have influence, and are at the point at which the positions and strengths of the arguments should result in an objective ruling.

A SCOTUS ruling that is favorable to the Arkansas appeal will be very important for pharmacy and patients, but much work remains to be done. Although the ruling has huge implications, the issue SCOTUS is addressing is very specific and narrow. It will be up to the profession of pharmacy and supportive legislators to apply and expand upon even a favorable ruling, and a continuing battle with the PBMs can be expected every step of the way. The PBMs have been able to evade and thwart previous challenges, and can be expected to develop strategies to circumvent a SCOTUS ruling that would slow/stop their momentum.

A ruling that is favorable to Arkansas should result in a cascade of reactivated and new similar legislative proposals in the many states that have the same concerns about PBM programs, but in which previous challenges have not been successful. States that have refused or have been reluctant to address the concerns of pharmacists and patients because of the likelihood of costly litigation in challenging the PBM/PCMA ERISA-escape strategy will be emboldened by a favorable ruling. More pharmacists will be more motivated to be actively engaged in promoting our professional role and our services for patients, in challenging the destructive prescription plans of the PBMs and health insurance companies, and in supporting and voting for legislators who understand and support our positions.

The PBMs still have wealth and influence. However, pharmacists and our professional organizations have the potential for greater influence – VOTES! However, our potential is far from being fulfilled, and that is OUR fault. As individual pharmacists, we must be more engaged in our profession and politically, we must hold our organizations more accountable for providing united and strong advocacy for the profession of pharmacy that is the basis for the existence of all of our organizations, we must get to know the candidates for legislative positions and mobilize support of those within our communities in electing legislators who will be advocates for optimum health care for their constituents and our services in providing it, and working with legislators in developing laws and regulations that will advance and protect the quality of health care. I do not want to think of the alternatives, and there may not be any!

THANK YOU to the pharmacists of Arkansas and others who have supported them for their dedication and perseverance in bringing these urgent concerns to the level of the Supreme Court.

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# New Drug Review

## Sarecycline hydrochloride
(Seysara – Almirall) *Antibacterial Agent*

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

### Indication:
Treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age or older.

### Comparable drugs:
Doxycycline, minocycline.

### Advantages:
- Has a narrow antibacterial spectrum and may be less likely to cause gastrointestinal adverse events.

### Disadvantages:
- Has not been directly compared with comparable drugs in clinical studies;
- Labeled indications are more limited.

### Most important risks/adverse events:
Contraindicated in patients with a known hypersensitivity to any of the tetracyclines; may cause adverse developmental effects if used in pregnant women; may cause permanent discoloration of the teeth if it is used during the second and third trimesters of pregnancy, infancy, childhood up to the age of 8 years, and in nursing mothers; use should be avoided in women attempting to conceive a child, and in male partners; photosensitivity (patients should be advised to avoid or minimize exposure to natural or artificial sunlight); central nervous system effects (light-headedness, dizziness, vertigo); intracranial hypertension (headache, visual disturbances; concomitant use with isotretinoin should be avoided); may depress plasma prothrombin activity and, in patients being treated with an anticoagulant, it may be necessary to reduce the dosage of the anticoagulant); concurrent use with penicillins should be avoided; absorption and activity may be reduced by multivalent cation-containing products (e.g., aluminum, magnesium, calcium, iron), and an appropriate interval should separate administration; inhibits P-glycoprotein (P-gp) and may increase the action of P-gp substrates (e.g., digoxin).

### Most common adverse events:
Nausea (3%), vulvovaginal fungal infections (1%).

### Usual dosage:
Administered once a day; 60 mg in patients weighing between 33 and 54 kg, 100 mg in patients weighing between 55 and 84 kg, and 150 mg in patients weighing between 85 and 136 kg; should be administered with a significant amount of fluid to reduce the possibility of esophageal irritation and ulceration.

### Product:
Tablets – 60 mg, 100 mg, 150 mg.

### Comments:
Sarecycline is the fifth tetracycline derivative to be approved for the oral treatment of acne vulgaris, joining doxycycline, minocycline, tetracycline, and demeclocycline. Unlike the other tetracyclines which have a broad spectrum of antibacterial activity, sarecycline has a narrow antibacterial spectrum. It spectrum of action includes Cutibacterium acnes, the bacterium most often implicated in the occurrence of acne, as well as certain staphylococci and streptococci. Its benefit in treating acne is attributed to its antibacterial and anti-inflammatory activities.

The effectiveness of sarecycline was evaluated in two 12-week placebo-controlled clinical trials, in which the co-primary efficacy endpoints were the percentage of patients with Investigator's Global Assessment (IGA) success (a score of clear [0] or almost clear [1], and 2-point decrease from baseline on IGA score at Week 12), and an absolute reduction from baseline in inflammatory lesion counts at Week 12. The IGA success in patients treated with sarecycline was 22% and 23% in the two studies, compared with 11% and 15% in those receiving placebo. The mean absolute reduction in inflammatory lesions was 15 and 16, compared with 10 and 11 in those receiving placebo.

Daniel A. Hussar

# The Language of God

Soon after it was published in 2006, I read the book, *The Language of God: A Scientist Presents Evidence for Belief*, by Francis S. Collins, the head of the Human Genome Project at that time, and now the Director of the National Institutes of Health. Dr. Collins is a geneticist and physician who shares in his book his journey from atheism to faith. He is an advocate for the themes that faith in God and faith in science can be harmonious, and that science does not conflict with the Bible, but that science enhances it. His book and his continuing accomplishments and presentations strongly support the integration of faith, reason, and science. I encourage you to read his book and know that you will find it to be a thought-provoking and learning experience.

On September 24, 2020, I had the opportunity to virtually attend the 2020 Templeton Prize Ceremony, a Prize that was established in 1972 by investor and philanthropist Sir John Templeton to recognize discoveries that yielded new insights about religion especially through science. Dr. Francis Collins is the 2020 Templeton Prize Laureate who was honored at this event that was very professionally planned and moderated by Heather Templeton Dill and Jennifer Templeton Simpson, the granddaughters of Sir John Templeton who continue the distinguished family legacy.

The announcement in May of the selection of the 2020 Templeton Prize Laureate includes the following comments from Dr. Collins:

> "As a Christian for 43 years, I have found joyful harmony between the scientific and spiritual worldviews, and have never encountered an irreconcilable difference."
>
> "Almost my every waking moment is consumed by the effort to find treatments and a vaccine for COVID-19. The elegant complexity of human biology constantly creates in me a sense of awe."
>
> "I learn and re-learn that God never promised freedom from suffering – but rather to be 'our refuge and strength, a very present help in trouble' (Psalm 46)."

At this time at which the brilliance and discoveries of Dr. Collins are being honored, his humility is also very evident in his statements and acceptance of the Templeton Prize, as exemplified by his recognition of and respect for God and His creation, and the challenges of what is still unknown about COVID-19 and other mysteries of life. From his book, *The Language of God*:

> "The God of the Bible is also the God of the genome. He can be worshipped in the cathedral or in the laboratory. His creation is majestic, awesome, intricate, and beautiful."

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