IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. **CIVIL ACTION NO.** 15-C-584

KAREN L. BOWLING, Secretary of the West Virginia Department of Health and Human Resources,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

Mylan Specialty L.P. ("Mylan Specialty") is entitled to a *status quo* preliminary injunction enjoining the West Virginia Department of Health and Human Resources' ("DHHR") implementation of a revised Medicaid Preferred Drug List ("PDL") effective April 1, 2015 (the "Revised PDL"), which would remove EpiPen® and EpiPen Jr.® epinephrine auto-injectors (together, "EpiPen®") as "preferred" drugs in the epinephrine auto-injector ("EAI") therapeutic class and replace them with a therapeutically inequivalent EAI called Auvi-Q®.

The Revised PDL was adopted by DHHR, by and through the Pharmaceuticals and Therapeutics Committee (the "P&T Committee"), in violation of the West Virginia Open Governmental Meetings Act, W. Va. Code § 6-9A-1 *et seq.* (the "Sunshine Act") as Mylan has learned from documents produced by DHHR in response to a February 27, 2015, West Virginia Freedom of Information Act request (the "FOIA Request") and in communications with the Bureau for Medical Services ("BMS"):

> (1) a December 3, 2014, e-mail from the State's consultant, Magellan Medicaid Administration ("Magellan"), to members of the P&T Committee informing them of efforts to educate West Virginia medical professionals on EpiPen® and Auvi-Q®, attached as Exhibit A, and

(2) During a February 28, 2015, meeting of the West Virginia Drug Utilization Review Committee, a representative of BMS confirmed to Dr. Margaret Wooddell of Mylan Specialty that, in advance of January 28, 2015, two doctors on the P&T Committee had drafted and sent a letter to West Virginia medical professionals advising them of the substitution of Auvi-Q® for EpiPen® in the preferred category of the EAI therapeutic class. [*See* Margaret Wooddell Aff. ¶ 33, attached as Exhibit B].

These actions reveal that the P&T Committee's recommendation of the Revised PDL, as well as subsequent steps taken toward its implementation, were taken prior to the P&T Committee's formal recommendation of the Revised PDL during its January 28, 2015, meeting and, accordingly, were made in violation of the Sunshine Act. And, yet other documents produced in response to the FOIA Request demonstrate why the decision was made outside of public view: the decision was made despite unresolved concerns about patient safety and costs raised by DHHR's own consultant, Magellan. Most remarkably, these documents likely only tell part of the story; DHHR's response to the FOIA Request was not only belated, it was also incomplete, and it is probable that other documents reflecting the arbitrary, capricious, and unlawful foundation for the Revised PDL remain undiscovered.[1]

Nonetheless, even the documents currently available to Mylan and to the Court demonstrate that the recommendation and adoption of the Revised PDL was made in violation of the Sunshine Act. The recommendation and adoption of the Revised PDL is accordingly void and invalid, and Mylan Specialty is entitled to an injunction enjoining its implementation.

I. INTRODUCTION

Mylan Specialty places patient safety, awareness, preparedness, and access as its top priorities, and its commitment to EpiPen® auto-injectors is grounded in those key principles. [Roger Graham Aff. ¶ 4, attached as Exhibit C]. EpiPen® has been the most prescribed EAI for

[1] DHHR claimed it had "lost" Mylan's FOIA request and only after repeated calls from counsel did DHHR produce an incomplete response to the request.

more than 25 years. [Wooddell Aff. ¶ 4]. Nationally, approximately 9 of every 10 scripts for an EAI are written for EpiPen®, and more than 60 million EpiPen® auto-injectors have been dispensed in the United States since its introduction. [Graham Aff. ¶ 9].

EAIs are not typical drug devices. They are emergency use products and, the distinct EAIs currently on the market are not the same, and they are not interchangeable. [Wooddell Aff. ¶¶ 20-22]. EAIs are emergency use products that differ in important ways, including in their design, administration, and in the instructions for their safe and effective use. [*Id.* at ¶ 20-21, 23]. Any confusion on how to administer an unfamiliar EAI during an emergency could result in negative health outcomes.

Mylan Specialty goes to great lengths to ensure that patients prescribed EpiPen® and their caregivers are properly trained to use it in an emergency situation. [*See* Graham Aff. ¶¶ 4-5]. In recognition of the vital importance of patient familiarity with his or her prescribed EAI, Mylan Specialty packages every EpiPen 2-Pak® and EpiPen Jr. 2-Pak® with a training device to enable patients, caregivers, and other users to practice the proper administration technique with this particular product.[2] [Wooddell Aff. ¶ 25] Moreover, more than 250 West Virginia schools currently participate in the EpiPen4Schools® program and, as a result, those schools have received more than 750 EpiPen® and EpiPen Jr.® EAIs free of charge. [*Id.* at ¶ 10] Mylan Specialty has also invested in training West Virginia school nurses about anaphylaxis and its treatment through the administration of EpiPen®. [*Id.*]

As a consequence, when Mylan Specialty learned that the P&T Committee would consider revisions to the EAI therapeutic class during its October 22, 2014, meeting, it sent representatives to inform the P&T Committee about the significant patient safety concerns

[2] Mylan Specialty has also developed several other useful resources, such as a training DVD, a smartphone app, and an informative product website, to educate patients, caregivers, and others on anaphylaxis and the use of EpiPen® as a first-line emergency treatment. [Wooddell Aff. ¶ 25; Graham Aff. ¶ 6]

associated with substituting one EAI for another that has been deemed therapeutically inequivalent by the United States Food and Drug Administration ("FDA"). [*Id.* at ¶ 32] And, when the P&T Committee tabled a motion to revise the EAI therapeutic class during that meeting based, in part, on a desire for additional information, Mylan Specialty contacted BMS to offer information the P&T Committee might find helpful. [*See* Nov. 5, 2014, and Nov. 11, 2014, E-mails From Thomas Letizia to Vicki Cunningham, attached as Exhibit D]. Finally, when Mylan Specialty learned that the P&T Committee would reconsider revisions to the EAI therapeutic class during its January 28, 2015, meeting, Mylan Specialty again sent representatives to educate the P&T Committee about the patient safety concerns regarding substitutability – concerns that have been highlighted by FDA, no less – that are unique to the EAI therapeutic class.

Even following the P&T Committee's recommendation at its January 28, 2015, meeting to remove EpiPen® from the preferred category in the EAI therapeutic class on the PDL and replace it with Auvi-Q® (the "Revised PDL"), Mylan Specialty continued its attempts to educate DHHR regarding the potentially deleterious effects of the Revised PDL on patient safety. On February 25, 2015, Mylan Specialty's Vice President, Global Medical Affairs, Dr. Rafael Muniz, sent Secretary Bowling and Acting Commissioner Beane a letter requesting that DHHR reconsider adoption and implementation of the Revised PDL in light of patient safety issues and retain EpiPen® as a "preferred" agent. [*See* Feb. 25, 2015, Letter from Muniz to Bowling and Beane, attached as Exhibit E]. Representatives from Mylan Specialty subsequently met with DHHR to further discuss these patient safety concerns and to educate DHHR on how access to EpiPen® has been preserved in other states in the interest of patient safety. [*See, generally*, Wooddell Aff. ¶ 33].

In addition, during this same time frame, representatives of DHHR also received a letter from Allergy & Asthma Network, the leading national nonprofit dedicated to ending needless death and suffering due to asthma, allergies and related conditions through public outreach. The letter, which was also collectively supported by six other recognized allergy advocacy organizations, respectfully requested that EpiPen® maintain its current preferred status on the West Virginia Medicaid formulary in order to prevent any barriers to access in a life-threatening circumstance. It also went further to explain its reasoning for getting involved, stating:

> Our question is simple … is the state of West Virginia or the P&T committee of West Virginia Medicaid prepared to face the mother who has lost her child because of this decision to limit access to the only product that child has ever been trained to use in order to save his life? … By excluding EpiPen from covered status, many patients will be forced to seek unscheduled office visits, ER visits, and hospitalizations due to the lack of familiarity and understanding of the alternative device. In fact, we believe the patient population most impacted by this decision is the one often at the highest risk and the most underserved … Rarely do we feel the need to voice our opinion on formulary decisions; however, in this instance we could not sit idly by and allow this to move forward without rallying our community and imploring you to reconsider your position.

[*See* Feb. 23, 2015, Letter from Tonya Winders to Brian Thompson and Cynthia Beane, attached as Exhibit F].

Food Allergy Research and Education ("FARE"), the leading national organization supporting individuals with food allergies, likewise contacted DHHR to state its position that "[b]ecause these [EAI] devices require unique training and have both technical and aesthetic differences, we support patients have equal access to all of these devices." [*See* Feb. 24, 2015, Letter from James R. Baker, Jr. to Karen L. Bowling, attached as Exhibit G].

But DHHR has been unreceptive at each step, and plans to implement the Revised PDL effective April 1, 2015, at which time the thousands of West Virginia Medicaid recipients who rely upon EpiPen® for the first-line treatment of anaphylaxis will effectively be required to

switch to Auvi-Q® instead – a device that is therapeutically inequivalent to EpiPen® and whose design, administration, and instructions for safe and effective use during an emergency are entirely different.[3]

What Mylan did not know at the time, however, was that its education efforts, and the education efforts of advocacy organizations, were futile. Based upon documents recently produced by DHHR in its (belated and deficient) response to a West Virginia Freedom of Information Act request several weeks after the statutorily-required deadline, Mylan Specialty now knows that the Revised PDL was adopted well in advance of the P&T Committee's January 28, 2015, meeting in violation of the Sunshine Act. A cursory review of this deficient document production demonstrates why the decision was made outside of public view: the decision was made despite unresolved concerns about patient safety and costs raised by DHHR's own consultant, Magellan.

Indeed, Magellan, DHHR's own consultant, warned about the proposed removal of EpiPen® Auto-Injector from the preferred category of the PDL: "It concerns me that this will impact kids and that means everyone would have to be taken off a product that they have known for so long…" [*See* Dec. 5, 2014, E-mail from Nina Bandali to Vicki Cunningham, attached as Exhibit H]. This echoes the safety concerns on which Mylan has attempted to focus the DHHR. Absent, however, from the record produced by DHHR, is any indication that the Agency made any effort to address this critical safety concern, let alone resolved it.

It is essential that, as contemplated by the Sunshine Act, implementation of the Revised PDL be preliminarily enjoined before the P&T Committee's unlawful recommendation is

[3] Mylan Specialty is not suggesting any safety issue with Auvi-Q®. Indeed, the FDA has found Auvi-Q® to be safe and effective. Mylan Specialty's point is to convey potential safety concerns that may occur when a patient tries to administer one EAI expecting the product to operate the same way as a different one for which he/she has been trained.

ultimately voided. Mylan Specialty has no adequate remedy at law to challenge implementation of the P&T Committee's arbitrary, capricious, and unlawful recommendation because there is no mechanism for administrative appeal. In addition, Mylan Specialty will suffer irreparable harm as a result of implementation of the P&T Committee's arbitrary, capricious, and unlawful recommendation.

Most significantly, thousands of West Virginia Medicaid recipients will be irreparably harmed as a consequence of the Revised PDL, which will effectively deprive them of the EpiPen® on which they rely for emergency medical treatment. Because EAIs are emergency use products administered by patients or caregivers irregularly and in high-stress, emergency situations, it is essential to patient safety that patients and caregivers be instructed on, and become practiced in, the use of their prescribed EAI. And, because each of the currently-marketed EAIs is visually and physically different, and presents distinct user operating principles, substitution of one EAI for another presents a real concern for patient safety: that a patient or caregiver will not receive instruction and retraining on the newly-prescribed EAI and will accordingly fail to properly administer the product during an emergency situation. Implementation of the Revised PDL accordingly places at risk of irreparable harm the thousands of West Virginia Medicaid recipients who effectively will be required to switch from EpiPen® to a new and unfamiliar device in the form of Auvi-Q®.

For these reasons, Mylan Specialty is entitled to a *status quo* preliminary injunction enjoining DHHR's implementation of the Revised PDL removing EpiPen® from the preferred category of the EAI therapeutic class and replacing it with Auvi-Q®. DHHR's actions, including those taken through BMS and the P&T Committee, are in violation of the Sunshine Act and should be accordingly invalidated and declared void.

II. STATEMENT OF FACTS

Mylan Specialty and EpiPen®

Mylan Specialty is a wholly-owned subsidiary of Mylan Inc., which has grown from a small pharmaceuticals distributor founded in White Sulphur Springs, West Virginia, in 1961, to a pharmaceutical manufacturer employing more than 3,000 West Virginians. It is the proud provider of EpiPen®, which has been the most prescribed EAI for more than 25 years; approximately 9 of every 10 scripts for an EAI are written for EpiPen®. In West Virginia, nearly 22,000 prescriptions for EpiPen® were written in 2014, representing a substantial portion of the prescribed EAIs for that period. [Wooddell Aff. ¶¶ 5-6; Graham Aff. ¶ 9].

EAIs such as EpiPen® are used to administer epinephrine, which is the first-line treatment for anaphylaxis – a life-threatening hypersensitivity (allergic) reaction that causes approximately 100 deaths each year. [Wooddell Aff. ¶¶ 7-8]. As many as 43 million Americans may be susceptible, including the 1 in 13 children estimated to have a food allergy – a common cause of anaphylaxis. [*Id.* at ¶ 8] Failure to rapidly receive treatment (sometimes within a matter of minutes), is directly associated with negative health outcomes, and, therefore, it is critically important that patients and caregivers administering EAIs in these emergency situations know how to adequately administer the products.

With EpiPen®, Mylan Specialty has made the need for continual training of patients, caregivers, and others, including physicians and other healthcare professionals, a primary focus. For example, every EpiPen 2-Pak® and EpiPen Jr. 2-Pak® is packaged with a training device to enable patients, caregivers, and other users to practice the proper administration technique with the product. [Woddell Aff. ¶ 25; Graham Aff. ¶ 5]. Mylan Specialty is continually assessing ways to improve user education and reinforce the proper use of its product.

The EpiPen4Schools® Program

In recognition of the importance of EAIs to treating anaphylaxis, Mylan Specialty launched the EpiPen4Schools® program in 2012. [Wooddell Aff. ¶ 9]. This nationwide program offers four free EpiPen® or EpiPen Jr.® EAIs to qualifying schools and, to date, more than 53,000 schools have enrolled in the program. [*Id.*] As part of its commitment to preparing schools for treating anaphylaxis, Mylan Specialty has also sponsored training for school nurses. [*Id.*]

More than 250 West Virginia schools currently participate in the EpiPen4Schools® program and, as a result, those schools have received more than 750 EpiPen® and EpiPen Jr.® EAIs free of charge. [Woddell Aff. ¶ 10]. Mylan Specialty has also invested in training West Virginia school nurses about anaphylaxis and its treatment through the administration of EpiPen®. [*Id.*]

The prevalence of anaphylaxis risk in our schools, as well as the importance of access to EAIs like EpiPen®, was demonstrated by a 2014 Mylan Specialty-sponsored survey of schools participating in the EpiPen4Schools® program. [*Id.* at ¶ 11]. The 6,000 schools that responded to the survey identified a total of 919 anaphylactic events during the 2013/2014 school year. [*Id.* at ¶ 12] Those schools indicated not only that more than 20% of the anaphylactic events occurred in individuals with no known history of life-threatening allergies, but also that anaphylaxis risk may be heightened among teens, who reflected approximately 50% of all anaphylactic events reported. [*Id.*] Most significantly, however, nearly 50% of the anaphylactic events were treated with an EpiPen® provided through the EpiPen4Schools® program. [*Id.* at ¶ 13]

EpiPen® and the EpiPen4Schools® program save lives.

EpiPen®, Auvi-Q®, and Therapeutic Inequivalence

There are currently four EAIs marketed in the United States: EpiPen® (Mylan Specialty L.P.); Auvi-Q® (sanofi-aventis US LLC); Adrenaclick® (Amedra Pharmaceuticals LLC); and Epinephrine injection, USP auto-injector (Lineage Therapeutics), the authorized generic to Adrenaclick® (the "Authorized Generic"). Each of the EAIs administers a single dose of either 0.3 or 0.15 mg of epinephrine. The 0.3-mg dose is intended for patients who weigh 30 kg or more, and the 0.15-mg dose is intended for patients who weigh 15 to 30 kg. The photographs and Table 1, below, reflect the visual and physical differences, as well as the distinct user operating principles and procedures, of these products.

EpiPen®

Auvi-Q®

Adrenaclick® / Authorized Generic

Table 1. Features of EAIs Currently Marketed in the U.S.

Product	Dose	Safety Caps to Remove Before Use	Color of Safety Cap/ Injection End	Built-in Needle Protection	Packaging and Dispensing	Instructions for Use
EpiPen/ EpiPen Jr	0.30/ 0.15 mg	1	Blue/Orange	Yes	2-pack with trainer	Remove EAI from carrier tube by opening the yellow cap (green cap for EpiPen Jr). Remove blue safety cap and administer by swinging and firmly pushing the orange tip against the outer thigh until it "clicks." Hold firmly against thigh for 10 sec
Auvi-Q	0.15/ 0.30 mg	1	Red/Black	Yes	2-pack with trainer	Follow voice instructions. Remove EAI from outer case and pull off red safety guard. Place black end against middle outer thigh, press firmly, and hold in place for 5 sec or until voice prompt
Adrenaclick	0.15/ 0.30 mg	2	Gray/Red	No (user must recap)	Single pack without trainer	Pull off gray caps at both ends. Put the red tip against middle thigh and press down until needle penetrates the skin. Hold EAI in place while slowly counting to 10
Epinephrine injection, USP auto-injector[a]	0.15/ 0.30 mg	2	Gray/Red	No (user must recap)	Single pack without trainer	Same as above

The FDA publishes its determination regarding therapeutic equivalence in its *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is commonly known as the "Orange Book." For the FDA, "[d]rug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling." Food and Drug Administration, *Preface to the 34th Edition of Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*, *available at* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm (last accessed Mar. 16, 2015).

With respect to EAIs, the FDA has assigned each of the distinct currently-marketed products a BX-rating, indicating that the Agency has concluded that the products are **not** therapeutically equivalent because there is insufficient data available to compare the relative

equivalence of these products.[4] As reflected in Table 1 and the photographs, above, these distinct products offer the same active ingredient (epinephrine), but are visually and physically different, and present distinct user operating principles and procedures such that each product is administered in a substantially different manner.

Importantly, EAIs are emergency use products administered by patients or caregivers on an irregular basis and then only in high-stress, emergency situations. The FDA has noted these factors specifically when considering potential product substitution for EAIs, cautioning that "it is particularly important to ensure that patients in an emergency situation can use the product safely and effectively in accordance with instructions provided for [a product] without additional physician intervention or retraining prior to use" of a different product. [Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Thomas K. Rogers, III, Executive Vice President, Regulatory Affairs, King Pharmaceuticals, Inc., Dkt. Nos. FDA-2007-P0128 and FDA-2009-P0040 (July 29, 2009), attached as Exhibit I].

Put simply, EAIs such as EpiPen® and Auvi-Q® are **not** therapeutically equivalent and, as emergency use products, present special patient safety concerns.

The West Virginia Medicaid Program

The Medicaid program was created in 1965 by Title XIX of Public Law 89-97, which established federal grants to help states finance medical care for persons with low incomes. Although federal law establishes certain baseline requirements for state Medicaid programs, the states have the flexibility to set up their own eligibility requirements, payments for services, and covered benefits subject to approval of their Medicaid plans by the Centers for Medicare and

[4] In addition, there appears to be no clinical evidence, such as from adequate and well-controlled, head-to-head clinical studies, or clinical experience that is sufficient to conclude Auvi-Q® offers a superior efficacy or safety profile as compared to EpiPen®.

Medicaid Services, a federal agency operating under the Secretary of the Department of Health and Human Services.

In West Virginia, the State Medicaid program is administered by BMS, which is part of and under the direct supervision of DHHR. As the agency responsible for the State Medicaid program, one of BMS's responsibilities is the administration of the West Virginia Medicaid Pharmacy Program, the mechanism by which West Virginia provides payment of certain covered outpatient drugs (typically, prescription drugs). Payment of covered outpatient drugs, however, is subject to certain limitations, the most significant of which is the preferred drug list, or PDL.

The State PDL is developed by the P&T Committee within BMS; Magellan provides assistance. The PDL is intended to improve therapeutic outcomes and cost efficiencies by encouraging the prescription of some drugs and discouraging the prescription of others. This is accomplished by separating drugs into "preferred" and "non-preferred" categories within a certain therapeutic class. Among other factors, the P&T Committee considers efficacy, effectiveness, adverse effects, and tolerability to determine whether a drug is superior, equivalent, or inferior relative to other drugs in the therapeutic class. A drug is deemed preferred if it provides a superior therapeutic outcome or if, as compared to other drugs within the class, it is more cost-efficient; a drug is deemed non-preferred if it provides an inferior therapeutic outcome or if, as compared to other drugs within the class, it is less cost-efficient.

To encourage their prescription over non-preferred drugs, preferred drugs have a significant advantage: preferred drugs are automatically reimbursable under the West Virginia Medicaid Pharmacy Program, whereas non-preferred drugs are reimbursable only with prior authorization. Because prior authorization must be requested by the dispensing pharmacist, prescriber, or the prescriber's designee upon demonstration of specific criteria, the practical

effect of the PDL is to ensure the substitution of a preferred drug for a non-preferred drug in the vast majority of cases.

EpiPen®, Auvi-Q®, and the PDL

Since its introduction, EpiPen® has been reimbursable under the State Medicaid Program without prior authorization. [Wooddell Aff. ¶ 31]. Effective April 1, 2015, however, the Revised PDL will move EpiPen® from the preferred to non-preferred category in the EAI therapeutic class while, at the same time, moving Auvi-Q® from the non-preferred to preferred category. The primary effect of the Revised PDL will be to make Auvi-Q® the preferred EAI for West Virginia Medicaid recipients and to make EpiPen® reimbursable only with prior authorization. The secondary effect of the Revised PDL will be to switch the thousands of West Virginia Medicaid recipients who currently rely on EpiPen® to Auvi-Q®.

Ostensibly, the P&T Committee made its recommendation to adopt and implement the Revised PDL during its January 28, 2015, meeting. The P&T Committee had considered revision of the EAI therapeutic class of the PDL during its October 22, 2015, meeting, but had tabled a motion to do so. That motion was taken back up and passed during the P&T Committee's January 28, 2015, meeting.

Mylan Specialty has since discovered, however, that the decision to adopt and implement the Revised PDL actually was made sometime between October 22, 2014, and January 28, 2015, in violation of the Sunshine Act. BMS has been taking action since at least January 1, 2015, to implement the substitution of Auvi-Q® for EpiPen® in the preferred category of the EAI therapeutic class in the Revised PDL. Among other action, BMS sent West Virginia medical professionals a newsletter, which predated the formal January 28, 2015, recommendation of the Revised PDL, in order to provide them with "lead time" to educate their patients. These actions

reflect a decision that could not have been made consistent with the requirements of the Sunshine Act and that is accordingly void.

Mylan Specialty's Unanswered FOIA Request to DHHR

Following the P&T Committee's recommendation of the Revised PDL, Mylan Specialty's counsel served a FOIA request on DHHR on February 27, 2015. [*See* FOIA Request, attached as Exhibit J]. Through the FOIA Request, Mylan Specialty sought to discover the basis for the P&T Committee's recommendation of the Revised PDL, including two specific justifications provided by DHHR in a February meeting with representatives from Mylan Specialty. Those justifications for the Revised PDL were as follows: (1) that the P&T Committee, with the assistance of Magellan, concluded that EpiPen® and Auvi-Q® were therapeutically equivalent and/or substitutable products, and (2) that the P&T Committee, with the assistance of Magellan, concluded that the West Virginia Medicaid Pharmacy Program would experience cost efficiencies as a result of replacing EpiPen® with Auvi-Q® in the preferred category in the EAI therapeutic class on the PDL.

Although the West Virginia Freedom of Information Act, W. Va. Code § 29b-1-1 *et seq.*, required DHHR to respond to the FOIA Request within five days, or by March 6, 2015, DHHR did not respond or produce responsive documents until March 20, 2015. And, even having responded, a review of the documents produced in response to the FOIA Request demonstrates that certain responsive documents were not captured by DHHR as part of its review or were improperly withheld (See *supra* note 1).

DHHR's untimely and incomplete response to the FOIA Request has frustrated Mylan Specialty's ability to exhume the real reasons for the P&T Committee's recommendation of the Revised PDL and to present those issues to DHHR and to the Court for resolution.

III. ARGUMENT

A. Standard for Injunctive Relief[5]

In determining whether a preliminary injunction should issue, West Virginia has adopted a four-part test from the federal courts. *See State By & Through McGraw v. Imperial Mktg.*, 196 W. Va. 346, 352 n. 8, 472 S.E.2d 792, 798 n. 8 (1996); *Jefferson Cnty Bd.of Educ. v. Jefferson Cnty. Educ. Ass'n*, 183 W. Va. 1, 24, 393 S.E.2d 653, 662 (1990) (quoting *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Bradley*, 756 F.2d 1048, 1054 (4th Cir. 1985); *Blackwelder Furniture Co. v. Seilig Mfg. Co.*, 550 F.2d 189 (4th Cir. 1977)). Under this four-part test, the party seeking a preliminary injunction "must demonstrate by a clear showing of a reasonable likelihood of the presence of irreparable harm the absence of any other appropriate remedy at law; and the necessity of a balancing of hardship test including: (1) the likelihood of irreparable harm to the plaintiff without the injunction; (2) the likelihood of harm to the defendant with an injunction; (3) the plaintiff's likelihood of success on the merits; and (4) the public interest." *Imperial Mktg.*, 196 W.Va. at 352 n. 8, 472 S.E.2d at 798 n. 8 (internal quotations omitted).

West Virginia has also followed the federal courts in considering the four factors as part of a "flexible interplay." *See Jefferson Cnty. Bd. of Educ.*, 183 W. Va. at 25, 393 S.E.2d at 662. In application, "flexible interplay" refers to the relationship between a balancing of the hardships and the requirement that a plaintiff show it is likely to succeed on the merits. If the balance of the hardships between the plaintiff and defendant "tips decidedly in favor of the plaintiff," a preliminary injunction will issue where the plaintiff has "raised questions going to the merits so serious, substantial, difficult, and doubtful, as to make them fair ground for litigation and thus for

[5] Mylan Specialty respectfully suggests that, as injunctive relief is an express statutory remedy under the Sunshine Act, W. Va. Code § 6-9A-6, the Court may issue a preliminary injunction without resorting to the typical four-part test adopted from the federal courts.

more deliberate investigation." *McClure*, 301 F. Supp. 2d at 569 (citing *Manning v. Hunt*, 119 F.3d 254, 263 (4th Cir. 1997)).

B. No Adequate Remedy at Law

The Secretary of DHHR is authorized to adopt a PDL under W. Va. Code § 9-15-15. There is no statutory provision – including in the State Administrative Procedures Act, W. Va. Code § 29a-1-1 *et seq.* – however, that provides for review of the P&T Committee's decisions with respect to the PDL. In fact, DHHR's website clearly indicates in its section on frequently asked questions that "PDL decisions may not be appealed." *Frequently Asked Questions Regarding the West Virginia Medicaid Preferred Drug List ("PDL")*, West Virginia Bureau for Medical Services, West Virginia Department of Health and Human Resources, Oct. 2014, *available at* http://www.dhhr.wv.gov/bms/Pharmacy/Pages/FAQ.aspx (last accessed Mar. 4, 2015). Under these circumstances, Mylan Specialty has no adequate remedy at law and is entitled to an injunction enjoining implementation of the Revised PDL.

C. Irreparable Harm

Absent *status quo* injunctive relief, as of April 1, 2015, DHHR will implement the Revised PDL, which arbitrarily, capriciously, and unlawfully removes EpiPen® from the preferred category of the EAI therapeutic class and replaces it with Auvi-Q®. Mylan Specialty will suffer irreparable harm to its reputation and will lose market share as a result of the P&T Committee's arbitrary, capricious, and unlawful recommendation. Most significantly, however, thousands of West Virginia Medicaid recipients will be irreparably harmed as a consequence of the Revised PDL, which will effectively deprive them of the EpiPen® on which they rely, and on which they have been specifically trained, for administration of life-saving emergency medical treatment.

1. Mylan Specialty will suffer irreparable harm to its reputation and goodwill among EpiPen® users and medical professionals.

As evidenced by its substantial market share in West Virginia for EAI prescriptions, Mylan Specialty has built an extraordinary reputation and an extraordinary amount of goodwill among medical professionals and its West Virginia users. It has further built upon this reputation and goodwill through its EpiPen4Schools® program which, through its presence in more than 250 West Virginia schools (or approximately 1/3 of all public schools), has provided teachers and school nurses with the resources and training to treat life-threatening anaphylaxis with EpiPen®. Implementation of the Revised PDL, however, threatens to harm Mylan Specialty's hard-earned reputation among both EpiPen® users and medical professionals and, accordingly, should be enjoined. [*See, generally*, Graham Aff. ¶¶ 11-12].

First, it is reasonable to expect that many of the users who will be switched from EpiPen® to Auvi-Q® under the Revised PDL will be upset that they can no longer receive the EAI with which they have become familiar and upon which they have relied for first-line treatment for anaphylaxis. It is further reasonable to expect that many of these users will transfer their anger and frustration to Mylan Specialty as the provider of EpiPen®, thereby diminishing Mylan Specialty's reputation and goodwill among its users. [*See, generally,* Graham Aff. ¶ 11].

Second, it is reasonable to expect that, rather than switch to Auvi-Q®, some current users of EpiPen® will ask their medical providers to seek prior authorization for continued reimbursement of EpiPen® under the West Virginia Medicaid Pharmacy Program. These prior reimbursement requests will impose additional burdens on medical providers, who likely will place at least some of the blame with Mylan Specialty. [*Id.*].

Third, the P&T Committee's recommendation to remove EpiPen® from the preferred category in the EAI therapeutic class of the PDL and replace it with Auvi-Q® stands to lead

some medical providers to mistakenly question EpiPen's® safety and efficacy, particularly if DHHR, BMS, and the P&T Committee do not educate medical professionals about the (supposedly purely cost-driven) basis for the change. These medical professionals may switch all of their patients, including non-Medicaid patients, to Auvi-Q® or another EAI under the erroneous impression that such products are safer or more effective than EpiPen®. Worse, these medical providers could question the safety and efficacy of other products from Mylan Specialty and discontinue their prescription. Such a result would be particularly concerning to Mylan Specialty, which takes patient safety, awareness, preparedness, and access extraordinarily seriously and is proud of its industry-leading accomplishments in these regards. [*See, generally, id.* at ¶¶ 4, 12].

These scenarios reflect real possibilities that would result in real harm to Mylan Specialty's hard-earned reputation and goodwill among EpiPen® users and medical professionals. And, as several courts have found, loss of goodwill and reputation constitutes irreparable harm for purposes of injunctive relief. *See, e.g., Envtl. Servs., Inc. v. Recycle Green Servs., Inc.*, 7 F. Supp. 3d 260, 278-79 (E.D.N.Y. 2014) ("The loss of good will constitutes irreparable harm ... The potential loss of customers in this case is irreparable through monetary damages because it cannot be quantified." (internal citations and quotations omitted)). For this reason, the implementation of the Revised PDL should be enjoined.

2. Mylan Specialty will suffer irreparable harm by virtue of lost market share in the EAI therapeutic class.

If DHHR implements the Revised PDL effective April 1, 2015, it is likely that EpiPen® will lose market share among West Virginia Medicaid recipients who are prescribed EAIs. And, even when Mylan Specialty prevails on the merits in this action, it will face extraordinary difficulties in recapturing this lost business. [*See, generally*, Graham Aff. ¶¶ 13-16].

First, EAIs like EpiPen® and Auvi-Q® are intended only for emergency use; they are used irregularly and have long shelf lives. As a consequence, it may be months or years before a person switched from EpiPen® to Auvi-Q® returns to his or her medical provider for a new prescription and Mylan Specialty is even presented the opportunity to recover its market share. [*Id.* at ¶ 16].

Second, and more significantly, EpiPen® and Auvi-Q® are not therapeutically equivalent. Accordingly, for the reasons described above, West Virginia Medicaid recipients who are switched from EpiPen® to Auvi-Q® must be trained in the safe and effective use of their new EAI. And, once these Medicaid recipients are retrained to use Auvi-Q®, most medical professionals will be loath to switch them back to EpiPen® for the same reasons Mylan Specialty has raised in opposition to the P&T Committee's recommendation: switching a patient from one EAI to another, absent compelling medical justification, risks confusing ingrained behaviors in the product's administration and places the patient at risk during emergency situations. [*Id.*].

As a consequence, it may be months or years before Mylan Specialty has the opportunity to recover market share lost to the implementation of the P&T Committee's arbitrary, capricious, and unlawful decision, if it has the opportunity at all. For this additional reason, the implementation of the Revised PDL should be enjoined.

3. Mylan Specialty will suffer unrecoverable monetary damages unless implementation of the Revised PDL is enjoined.

If implementation of the Revised PDL is not enjoined, Mylan Specialty will suffer monetary damages as a direct result of the loss of market share described, above. [Graham Aff. ¶ 14]. Although the availability of money damages typically would not support a finding of irreparable harm, this is not the typical case. In this case, Mylan Specialty is precluded from

recovering money damages from DHHR, which, as an agency of the State, is immune from suit under Article VI, Section 35 of the State Constitution.[6] And, as several courts have recognized, "[i]mposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury." *Chamber of Commerce of U.S. v. Edmondson*, 594 F.3d 742, 770-71 (10th Cir. 2010); *see also Crowe & Dunlevy, P.C. v. Stidham*, 640 F.3d 1140, 1157 (10th Cir. 2011); *Feinerman v. Bernardi*, 5558 F. Supp. 2d. 36, 51 (D.D.C. 2008) (Where "the plaintiff in question cannot recover damages from the defendant due to the defendant's sovereign immunity ... any loss of income suffered by a plaintiff is irreparable *per se*." (internal citations omitted)); For this additional reason, the implementation of the Revised PDL should be enjoined.

4. West Virginia Medicaid recipients will suffer irreparable harm unless implementation of the Revised PDL is enjoined.

Implementation of the Revised PDL will irreparably harm the thousands of West Virginia Medicaid recipients who, having become familiar with the use of EpiPen®, will be forced to switch to a new and unfamiliar product in the form of Auvi-Q®. EpiPen® and Auvi-Q® are <u>not</u> therapeutically equivalent and, accordingly, are not substitutable. A former EpiPen® user who is given Auvi-Q® without retraining is at increased risk of misuse, [7] which can lead to the delayed or failed administration of epinephrine and, in turn, to negative health outcomes.

---

[6] There are several important exceptions to the State's immunity under Article VI, Section 35 of the State Constitution. The most significant exception is that which permits Mylan Specialty to bring this action: "Despite provisions of Section 35 of Article VI of the West Virginia Constitution, which prohibits the State from being made a defendant in any court of law or equity, mandamus may be employed to compel a state officer, who has acted arbitrarily, capriciously, or outside the law, to perform his lawful duties. " Syl. Pt. 1, *State ex rel. Ritchie v. Triplett*, 160 W. Va. 599, 236 S.E.2d 474 (1977). None of the exceptions, however, would permit Mylan Specialty to recover money damages against DHHR in this action.

[7] FDA has noted this potential consequence when considering potential product substitution for EAIs, cautioning that "it is particularly important to ensure that patients in an emergency situation can use the product safely and effectively in accordance with instructions provided for [a product] without additional physician intervention or retraining prior to use" of a different product. Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Thomas K. Rogers, III, Executive Vice President, Regulatory Affairs, King Pharmaceuticals, Inc., Dkt. Nos. FDA-2007-P0128 and FDA-2009-P0040 (July 29, 2009), attached as <u>Exhibit 1</u>.

In *Nemnich v. Stangler*, the District Court of the Western District of Missouri considered similar issues in the context of cuts in dental coverage under Missouri's state Medicaid program. No. 91-4517-cv-c-5, 1992 WL 178963 (W.D. Mo. Jan. 7, 1992). The *Nenmich* court concluded that, where "[p]eople may die as a result of defendants' actions," irreparable harm would result to Medicaid recipients in the absence of an injunction. *Id.* at *2. Likewise, several other courts from across the federal circuits have held that deprivation or elimination of needed care under state Medicaid programs constitutes irreparable harm. *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1342 (S.D. Fla. 2006) (collecting cases). This Court may reach a similar conclusion regarding the substitution of Auvi-Q® for EpiPen® in this case, and for this additional reason, the implementation of the Revised PDL should be enjoined.

D. Likelihood of Success on the Merits

Mylan Specialty is likely to succeed on the merits because the Revised PDL was adopted in violation of the Sunshine Act.

1. DHHR's response to the FOIA Request reveals that BMS was taking official action to implement the Revised PDL prior to its formal recommendation on January 28, 2015.

The P&T Committee is a governing body within the meaning of the Sunshine Act, W. Va. Code § 6-9A-1 *et seq.* And, as a governing body, the P&T Committee is required, with limited and inapplicable exceptions, to take official action and make decisions in regularly noticed public meetings. DHHR and BMS were well aware of this fact, as indicated in the documents produced by DHHR in response to the FOIA Request. In November 5, 2014, e-mail to its consultant, Magellan, the Director of Pharmacy Services for BMS wrote: "I am confused about the [P&T] Committee's intention. I heard they want us to have time to do education, but we can't educate if they haven't made a decision." [*See* Nov. 5, 2014, E-mail from Vicki

Cunningham to Nina Bandali, attached as Exhibit K]. Nonetheless, despite its own recognition of the impropriety, BMS was taking action to implement the Revised PDL in violation of the Sunshine Act prior to January 28, 2015.

On December 3, 2014, Nina Bandali, the State's consultant at Magellan e-mailed the members of the P&T Committee a copy of a December 2014 newsletter to West Virginia medical professionals that included a table comparing EpiPen® and Auvi-Q®. [*See* Dec. 3, 2014, E-mail from Nina Bandali, attached as Exhibit A].[8] The clear implication from Ms. Bandali's e-mail is that the comparative table in the December 2014 newsletter was included in response to the P&T Committee's request at the October 22, 2014, meeting that West Virginia medical professionals receive education about the distinctions between EpiPen® and Auvi-Q® [*Id.*]. This education, of course, was wholly improper in light of the P&T Committee's failure to take formal action with respect to the EAI therapeutic class during its October 22, 2014, meeting.

Additionally, Mylan Specialty has discovered that a letter was sent to West Virginia Medical professionals prior to January 28, 2015, in which the removal of EpiPen® as a preferred drug and its replacement with Auvi-Q® was announced as being effective January 1, 2015. The preparation and transmittal of this letter was confirmed to Dr. Margaret Wooddell during a February 28, 2015, meeting of the West Virginia Drug Utilization and Review Committee. [Wooddell Aff. ¶ 33].

By taking these actions to implement Auvi-Q® as a preferred drug prior to its regularly-scheduled January 28, 2015, meeting, BMS (and by extension, the P&T Committee) took official action regarding the EAI therapeutic class in executive session or at another meeting that was not properly noticed or open to the public. The recommendation of the Revised PDL is accordingly void and invalid, and its implementation should be enjoined.

[8] Ms. Bandali's e-mail mistakenly refers to the newsletter as having been sent in December 2015.

2. *The decision to adopt and implement the Revised PDL was made in violation of the Sunshine Act so as to shield from public view its arbitrary, capricious, and unlawful foundation.*

Review of even the deficient production made in response to the FOIA Request demonstrates why the decision was made outside of public view: the decision was made without a reasoned basis and despite safety and cost concerns raised by DHHR's own consultant, Magellan.

First, although the P&T Committee effectively (and erroneously) determined that EpiPen® and Auvi-Q® are therapeutically equivalent – and thus substitutable – products, the State's own consultant at Magellan stated that "[i]t concerns me that this [removing EpiPen® Auto-Injector from the preferred category of the PDL] will impact kids and that means everyone would have to be taken off a product that they have known for so long…" [*See* Exhibit K]. This concern is consistent with the FDA's evaluation of substitutability for these distinct products, where it has cautioned with respect to EAIs that "it is particularly important to ensure that patients in an emergency situation can use the product safely and effectively in accordance with instructions provided for [a product] without additional physician intervention or retraining prior to use" of a different product. Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Thomas K. Rogers, III, Executive Vice President, Regulatory Affairs, King Pharmaceuticals, Inc., *supra.*

Second, based upon evaluations from Magellan and the Sovereign States Drug Coalition, of which West Virginia is a member, the State's own consultants suggested that West Virginia would have difficulty switching a sufficient number of EpiPen® users to Auvi-Q® to justify the Revised PDL. [*See* Oct. 9, 2014, Sovereign States Drug Coalition Memorandum, attached as Exhibit L]. Indeed, the Sovereign States Drug Coalition cautioned that, absent a substantial

swing in market share from EpiPen® to Auvi-Q®, most states would actually see *increased* spending in the EAI therapeutic class if they did not retain the status quo. [*Id.*] For West Virginia, Magellan expressed its concerns that the State would be unable to reach such thresholds.

Based upon its own consultants' evaluation of the patient safety and cost concerns presented by the Revised PDL, it is unsurprising that the P&T Committee wished to make its decision outside the public view. These actions by DHHR, BMS, and/or the P&T Committee, however, are in violation of the requirements under the Sunshine Act, and the Court accordingly is empowered to invalidate the Revised PDL and enjoin its implementation. *See* W. Va. Code §§ 6-9A-3 and 6-9A-6.

E. <u>The Public Interest</u>

Issuance of an injunction is consistent with the public interest because it will protect the public's interest in open governmental affairs, generally, and West Virginia Medicaid recipients' interest in access to EpiPen® as first-line treatment for life-threatening anaphylaxis, specifically.

1. The public interest favors an injunction to enjoin decisions that were made in violation of the Sunshine Act.

When it enacted the Sunshine Act, the West Virginia Legislature chose to include a lengthy declaration of the policy considerations underlying the legislation. Of particular relevance are the Legislative declarations excerpted below:

> The Legislature hereby further finds and declares that the citizens of this state do not yield their sovereignty to the governmental agencies that serve them. The people in delegating authority do not give their public servants the right to decide what is good for them to know and what is not good for them to know. The people insist on remaining informed so that they may retain control over the instruments of government created by them.
>
> Open government allows the public to educate itself about government decisionmaking through individuals' attendance and participation at government

> functions, distribution of government information by the press or interested citizens, and public debate on issues deliberated within the government.
>
> Public access to information promotes attendance at meetings, improves planning of meetings, and encourages more thorough preparation and complete discussion of issues by participating officials. The government also benefits from openness because better preparation and public input allow government agencies to gauge public preferences accurately and thereby tailor their actions and policies more closely to public needs.

W. Va. Code § 6-9A-1 *et seq.*

As this legislative declaration makes apparent, it is *essential* that governmental affairs be conducted openly so as to ensure that the government serves the needs of its citizens and the public interest. And, this is precisely what failed to happen in this case. By taking action to adopt and implement the Revised PDL outside the requirements of the Sunshine Act, DHHR (and by extension, BMS and the P&T Committee) shielded from public view the arbitrary, capricious, and unlawful foundation for its action. The public interest accordingly favors an injunction enjoining DHHR, BMS, and/or the P&T Committee's unlawful action.

2. The public interest favors an injunction to safeguard West Virginia Medicaid recipients' access to EpiPen®, with which those recipients have become familiar and upon which they rely as a first-line treatment for life threatening anaphylaxis.

"Courts have frequently found that it is in the public interest to issue an injunction in connection with the Medicaid Act." *Texas Children's Hosp. v. Burwell*, No. 14-2060, 2014 WL 7373218, at *16, --- F. Supp. 3d --- (D.D.C. Dec. 29, 2014) (collecting cases). Among other factors, Courts have recognized that "there is a robust public interest in safeguarding access to health care for those eligible for Medicaid, whom Congress has recognized as 'the most needy in the country.'" *Id.* (quoting *Indep. Living Ctr. v. Maxwell-Jolly*, 572 F.3d 644, 659 (9th Cir. 2009), *vacated on other grounds by Douglas v. Indep. Living Ctr.*, --- U.S. ---, 132 S.Ct. 1204 (2012). This is precisely the public interest at stake in this litigation.

If implemented, the Revised PDL effectively will require medical professionals to substitute Auvi-Q® for the vast majority of the thousands of West Virginia Medicaid recipients who have become comfortable with, and reliant upon, EpiPen® as a first-line treatment for life-threatening anaphylaxis. And, although substitution of drugs may be appropriate in certain instances to improve therapeutic outcomes or improve cost efficiencies, it is fundamentally inappropriate in the case of therapeutically inequivalent emergency-use products like EpiPen® and Auvi-Q®.

EpiPen® and Auvi-Q® are intended for use solely in a medical emergency where a patient is suffering from a life-threatening allergic reaction. Failure to rapidly receive treatment (sometimes within a matter of minutes), is directly associated with negative health outcomes, and, therefore, it is critically important that patients and caregivers administering EAIs in these emergency situations know how to adequately administer the products. If a patient or caregiver who has been instructed by a physician and trained to administer EpiPen® is switched to Auvi-Q®, as the Revised PDL would effectively require, the patient or caregiver likely will not know how to use the product absent retraining. And, it is not difficult to imagine that some of these patients or caregivers will not receive adequate retraining, resulting in delayed product administration or misuse in times of emergency.

The question, then, is how many patients will experience negative outcomes as a result of implementation of the Revised PDL? Mylan Specialty submits that any number is too many; the public interest favors safeguarding Medicaid recipients' access to the EAI upon which they have become reliant for emergency treatment, and an injunction should be granted accordingly.

IV. CONCLUSION

The P&T Committee's recommendation of the Revised PDL was made in violation of the Sunshine Act in order to shield from public scrutiny the arbitrary, capricious, and unlawful foundation for its decision. The State's own Medicaid consultant, Magellan, recognized the deleterious effect that the Revised PDL would have on West Virginia Medicaid recipients who have been prescribed and rely upon EpiPen®. Magellan further expressed concerns regarding the State's ability to generate the shift in market share necessary to break even on the substitution of Auvi-Q® for EpiPen®. Notwithstanding these concerns, the P&T Committee recommended adoption of the Revised PDL, which will place at risk the health of those West Virginia Medicaid recipients whose medical providers effectively will be required to substitute Auvi-Q® for the EpiPen® auto-injector upon which they have become reliant. Mylan Specialty is entitled to an injunction enjoining that decision, as well as its implementation, until the Court can rule on the merits of Mylan Specialty's Sunshine Act claim and its request for declaratory relief.[9]

WHEREFORE, for the foregoing reasons, Mylan Specialty respectfully requests that the Court enter a *status quo* preliminary injunction enjoining the implementation of revisions to the West Virginia Medicaid Pharmacy Program's preferred drug list, which revisions are set to be effective April 1, 2015, and which would remove EpiPen® and EpiPen Jr.® epinephrine auto-injectors from the "preferred " category of the epinephrine auto-injector therapeutic class and replace them with Auvi-Q®, plus such other relief as the Court deems just and proper.

[9] In addition, DHHR should comply with its obligations under the West Virginia of Freedom of Information Act and produce additional documents that were inadvertently or inappropriately withheld.

MYLAN SPECIALTY L.P.

By Spilman Thomas & Battle, PLLC

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Joseph V. Schaeffer (WVSB #: 12088)
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304.291.7920
304.291.7979 (Facsimile)

7146399

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. **CIVIL ACTION NO. _____**

KAREN L. BOWLING, Secretary of the West Virginia Department of Health and Human Resources,

Defendant.

CERTIFICATE OF SERVICE

I, James A. Walls, hereby certify that service of the foregoing **MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION** has been made by hand-delivery on this 25th day of March, 2015 upon the following:

Secretary Karen L. Bowling, in her official capacity
West Virginia Department of Health and Human Resources
One Davis Square, Suite 100 East
Charleston, West Virginia 25301

Patrick Morrisey, Esq.
Office of the West Virginia Attorney General
State Capitol Complex,
Bldg. 1, Room E-26
Charleston, WV 25305

James A. Walls (WVSB #: 5175)

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. CIVIL ACTION NO. _____

KAREN L. BOWLING, Secretary
of the West Virginia Department
of Health and Human Resources,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT A

Cunningham, Vicki M

From: Bandali, Nina <NBandali@magellanhealth.com>
Sent: Wednesday, December 03, 2014 10:56 AM
To: rstanton@marshall.edu; gromem@Frontier.com; rlfdo@hotmail.com; jeffashley@suddenlink.net; sbrown@cchcwv.com; kinesfamilypharmacy@frontier.com; bradley.henry@camc.org; elbrn6e21@msn.com; fitzpatrickk@wvuhealthcare.com; mlonsinger@gmail.com; katedforman@gmail.com
Cc: Cunningham, Vicki M; Hopkins, William B; Thompson, Brian M; Sorvig, Richard D; Goodnight, Gail J; Perri, Giovannino A.
Subject: WV December 2014 Quarterly Newsletter
Attachments: WestVirginia_Newsletter V3N4_4Q2014.pdf

Hello everyone!

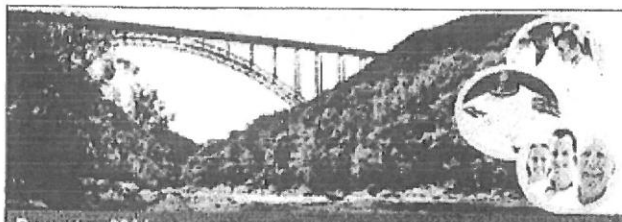
I would like to take this opportunity to welcome the new members and welcome everyone back from the Thanksgiving break! Hope everyone had a nice holiday.

Now to get back to business...during the October 22nd P&T meeting, the Committee requested that the Bureau provide additional information to educate providers about Epipen and Auvi-Q. Attached please find the December 2015 provider newsletter. We have incorporated a brief comparative table regarding Epipen vs. Auvi-Q. As a reminder, the class will be re-reviewed during the January 28, 2015 P&T meeting.

Please let me know if you have any questions or comments.

Thanks,
Nina

Nina Bandali, Pharm.D.
Clinical Project Manager
Magellan Health Services
Phone: 678-587-5080
Fax: 866-562-2735
Email: nbandali@magellanhealth.com



West Virginia Medicaid
Pharmacy Solutions

December 2014 Volume 3, Number 4

WEST VIRGINIA MEDICAID PHARMACY DEPARTMENT

http://www.dhhr.wv.gov/bms/Pharmacy

PROVIDER SERVICES

888-483-0793
888-483-0801 (Pharmacy)
304-348-3360
Monday – Friday
8:00 am until 5:00 pm

PHARMACY HELP DESK& PHARMACY PRIOR AUTHORIZATION (RATIONAL DRUG THERAPY PROGRAM)

800-847-3859 (Phone)
800-531-7787 (Fax)
Monday – Saturday
8:30 am until 9:00 pm
Sunday 12:00 pm until 6:00 pm

MEMBER SERVICES

888-483-0797
304-348-3365
Monday – Friday
8:00 am until 5:00 pm

PREFERRED DRUG LIST

For a copy of the most recent preferred drug list, visit:
http://www.dhhr.wv.gov/bms/Pharmacy/Pages/pdl.aspx

STATE MAXIMUM ALLOWABLE COST (SMAC)

SMAC Review Form:
http://www.dhhr.wv.gov/bms/Pharmacy/Pages/smac.aspx
Please refer questions to Magellan at 1-800-763-7382 or e-mail to StateSMACProgram@magellanhealth.com

SELF-INJECTED EPINEPHRINE PRODUCTS

Anaphylaxis is an acute, life-threatening medical emergency with many potential triggers such as food, medications, insect stings and bites, and latex. According to the 2010 National Institute of Allergy and Infectious Diseases (NIAID)-Sponsored Food Allergy Guidelines, intramuscular epinephrine is the treatment of choice for all instances of anaphylaxis resulting from food or any other cause.[1] The following is a comparative table which includes information on both Epipen® and Auvi-Q®.

	Epipen[2]	Auvi-Q[3,4]
Initial U.S. Approval	1939	2012
Active Ingredient	epinephrine	epinephrine
Dosage	Inject intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. • Patients greater than or equal to 30 kg (approximately 66 pounds or more): EpiPen 0.3 mg • Patients 15 to 30 kg (33 pounds to 66 pounds): EpiPen Jr 0.15 mg	Inject intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. • Patients greater than or equal to 30 kg (approximately 66 pounds or more): Auvi-Q 0.3 mg • Patients 15 to 30 kg (33 pounds to 66 pounds): Auvi-Q 0.15 mg
How Supplied	• two 0.3 mg auto-injectors and a single trainer • two 0.15 mg auto-injectors and a single trainer	• two 0.3 mg auto-injectors and a single trainer • two 0.15 mg auto-injectors and a single trainer
Training Device Included?	Yes	Yes
Size	Length: 6.25" including the closed cap Width: 1.4"	Length: 3 3/8" Width: 2"
Audible voice instructions?	No	Yes

Epinephrine auto-injector is also currently available on the market. This product is not AB-rated to either Epipen or Auvi-Q. A generic for Epipen is expected in June 2015. As the number of prescriptions written to treat allergic reactions grows so does the number of products that are used to treat the condition.

The information provided herein is for informational purposes only and is not intended to replace medical advice offered by physicians.

[1] Boyce JA, Asa'ad A, Burks AW, et al. Guidelines for the diagnosis and management of food allergy in the United States: Report of the NIAID-Sponsored Expert Panel. J Allergy Clin Immunol. 2010; 126 (6 Supp): S1-58. Available at: http://www.niaid.nih.gov/topics/foodallergy/clinical/Pages/default.aspx. Accessed November 18, 2014.
[2] EpiPen/EpiPen Jr. [package insert]. Columbia, MD; Mylan; May 2014.
[3] Auvi-Q [package insert]. Bridgewater, NJ; Sanofi-Aventis; September 2012.
[4] Auvi-Q. Available at: http://www.auvi-q.com/epinephrine-auto-injector-size. Accessed November 18, 2014.

Upcoming Preferred Drug List (PDL) Changes

Please be advised that the Bureau for Medical Services, based on recommendations made at the October 22, 2014 meeting of the West Virginia Medicaid Pharmaceutical & Therapeutics Committee, is making the changes listed below to the Preferred Drug List (PDL). The complete PDL with criteria is available on the Bureau's website at http://www.dhhr.wv.gov/bms/Pharmacy/Pages/pdl.aspx.

On January 1, 2015, the following changes will be effective:

Drug Class	The following products will become preferred products:	The following products will become non-preferred products and require prior authorization (PA):
Angiotensin Modulator Combinations	• Azor	
Anti-Allergens, Oral		• Grastek • Ragwitek
Antiparasitics, Topical	• Natroba	• permethrin cream
Antipsoriatics, Topical	• calcipotriene ointment	• Dovonex
Antipsychotics, Atypical	• Risperdal Consta	
Cytokine and CAM Antagonists		• Simponi
Glucocorticoids, Inhaled		• Flovent Diskus • Flovent HFA Pulmicort Flexhaler
Hepatitis B Treatments	• Tyzeka	
Hyperparathyroid Agents	• paricalcitol	Zemplar
Hypoglycemics, Incretin Mimetics/Enhancers	• Jentadueto	
Immune Globulins, IV	• Gammaplex	
Immunomodulators, Topical & Genital Warts		• Condylox solution
Immunosuppressives, Oral	• sirolimus	
Intranasal Rhinitis Agents	• Astepro	
Irritable Bowel Syndrome	• Amitiza • Linzess	• Lotronex
Laxatives and Cathartics	• Colyte • Golytely • Nulytely • PEG3350	• Halflytely-Bisacodyl • Moviprep • Osmoprep • Prepopik • Suprep
Lipotropics, Other		• Tricor • Trilipix
Lipotropics, Statins	• Crestor	• Advicor • amlodipine/atorvastatin • Lescol • Lescol XL • Simcor
Macrolides/Ketolides	• Biaxin XL	
Multiple Sclerosis Agents	• Extavia	• Betaseron • Rebif • Rebif Rebidose
Neuropathic Pain	• Lidoderm	
NSAIDs	• Voltaren gel	
Ophthalmics, Anti-Inflammatories-Immunomodulators		• Restasis
Steroids, Topical Low		• fluocinolone oil

Thank you for helping West Virginia Medicaid members retain access to prescription coverage by selecting drugs on the preferred drug list whenever possible.

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. CIVIL ACTION NO. _____

KAREN L. BOWLING, Secretary
of the West Virginia Department
of Health and Human Resources,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S
MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT B

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. **CIVIL ACTION NO. _____**

KAREN L. BOWLING, Secretary of the West Virginia Department of Health and Human Resources,

Defendant.

AFFIDAVIT OF MARGARET WOODDELL PhD MBA

I, Margaret J. Wooddell, being duly sworn, do depose and say as follows:

1. I am above the age of eighteen years and not subject to any legal disabilities. I make the following statements based on my personal knowledge, upon information provided to me by employees who report to me as part of their normal business duties, and upon review of documents and information maintained by my employer, Mylan Specialty L.P. ("Mylan Specialty") in the regular course of its business.

2. I am employed as Senior Director, Global Medical Affairs at Mylan Specialty and have been in that position since June 2014. In my current position, I am responsible for overseeing the EpiPen® and EpiPen Jr.® epinephrine auto-injectors (together, "EpiPen®") through, among other things, the provision of scientific and medical oversight. I am also familiar with the EpiPen4Schools® program.

3. As part of my responsibilities for overseeing EpiPen® for Mylan Specialty, I am also familiar with the other epinephrine auto-injector ("EAI") products currently marketed in the United States: Auvi-Q® (sanofi-aventis US LLC); Adrenaclick® (Amedra Pharmaceuticals

LLC); and Epinephrine injection, USP auto-injector (Lineage Therapeutics), the authorized generic to Adrenaclick®.

Mylan Specialty and EpiPen®

4. Mylan Specialty is the proud provider of EpiPen®, which has been the most prescribed EAI for more than 25 years.

5. Nationally, approximately 9 of every 10 scripts for an EAI are written for EpiPen®, and more than 60 million EpiPen® auto-injectors have been sold in the United States since its introduction.

6. In West Virginia, nearly 22,000 total prescriptions for EpiPen® were written in 2014, representing a substantial portion of all prescribed EAIs for that period. Included in that figure are more than 7,000 EpiPen® prescriptions written for West Virginia Medicaid recipients, representing an even more significant Medicaid market share.

7. EAIs like EpiPen® are used to administer epinephrine, which is the first-line treatment for anaphylaxis.

8. Anaphylaxis is a life-threatening hypersensitivity (allergic) reaction that causes an estimated 100 deaths each year. As many as 43 million Americans may be susceptible, including the 1 in 13 children estimated to have a food allergy – a common cause of anaphylaxis.

The EpiPen4Schools® Program

9. In recognition of the importance of EAIs to treating anaphylaxis, Mylan Specialty launched the EpiPen4Schools® program in 2012. This nationwide program offers four free EpiPen® or EpiPen Jr.® EAIs to qualifying schools and, to date, more than 53,000 schools have enrolled in the program. As part of its commitment to preparing schools for treating anaphylaxis, Mylan Specialty has also sponsored training for school nurses.

10. More than 250 West Virginia schools currently participate in the EpiPen4Schools® program and, as a result, have received more than 750 EpiPen® and EpiPen Jr.® EAIs free of charge. Mylan Specialty has also trained two nurses on the treatment of anaphylaxis who, in turn, educate West Virginia school nurses on the condition, including its treatment through the administration of EpiPen®.

11. In 2014, Mylan Specialty sponsored a survey study of anaphylaxis risk and treatment among the schools participating in the EpiPen4Schools® program.

12. The 6,000 schools that responded to the survey identified a total of 919 anaphylactic events during the 2013/2014 school year. Those schools indicated not only that more than 20% of the anaphylactic events occurred in individuals with no known history of life-threatening allergies, but also that anaphylaxis risk may be heightened among teens, who reflected approximately 50% of all anaphylactic events reported.

13. Most significantly, however, nearly 50% of the anaphylactic events were treated with an EpiPen® provided through the EpiPen4Schools® program.

EpiPen®, Auvi-Q®, and Therapeutic Inequivalence

14. Medical professionals, including doctors and pharmacists, use therapeutic classes to classify drugs according to the medical condition they are intended to treat. EAIs, for example, are part of an epinephrine auto-injector therapeutic class, meaning that they are intended for the treatment of anaphylaxis.

15. Although drugs may share a therapeutic class, they are not necessarily therapeutically equivalent.

16. Therapeutic equivalence is a separate concept that, in simple terms, reflects the extent to which one drug can be substituted for another seamlessly and without any retraining.

17. For the FDA, "[d]rug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling." Food and Drug Administration *Preface to the 34th Edition of Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).*

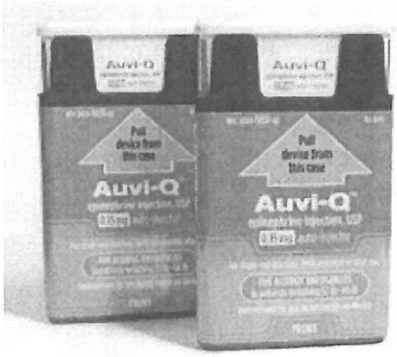
18. The FDA publishes its determination regarding therapeutic equivalence in its *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is commonly known as the "Orange Book."

19. With respect to EAIs, the FDA has assigned each of the distinct currently-marketed products, the EpiPen® Auto-Injector, Auvi-Q®, and the product marketed under the Adrenaclick® tradename (or without a tradename as epinephrine injection), a BX-rating, indicating that the Agency has concluded that the products are **not** therapeutically equivalent.[1]

20. As reflected in Table 1 and the photographs, below, these distinct products offer the same active ingredient (epinephrine), but are visually and physically different, and present distinct user operating principles and procedures such that each product is administered in a substantially different manner.

[1] The product marketed without a tradename as epinephrine injection and with a tradename as Adrenaclick® is marketed under the same approved application and would be therapeutically equivalent to each other, but not to EpiPen® or Auvi-Q®.

EpiPen®



Auvi-Q®

Adrenaclick®

Table 1. Features of EAIs Currently Marketed in the U.S.

Product	Dose	Safety Caps to Remove Before Use	Color of Safety Cap/ Injection End	Built-in Needle Protection	Packaging and Dispensing	Instructions for Use
EpiPen/ EpiPen Jr	0.30/ 0.15 mg	1	Blue/Orange	Yes	2-pack with trainer	Remove EAI from carrier tube by opening the yellow cap (green cap for EpiPen Jr). Remove blue safety cap and administer by swinging and firmly pushing the orange tip against the outer thigh until it "clicks." Hold firmly against thigh for 10 sec
Auvi-Q	0.15/ 0.30 mg	1	Red/Black	Yes	2-pack with trainer	Follow voice instructions. Remove EAI from outer case and pull off red safety guard. Place black end against middle outer thigh, press firmly, and hold in place for 5 sec or until voice prompt
Adrenaclick	0.15/ 0.30 mg	2	Gray/Red	No (user must recap)	Single pack without trainer	Pull off gray caps at both ends. Put the red tip against middle thigh and press down until needle penetrates the skin. Hold EAI in place while slowly counting to 10
Epinephrine injection, USP auto-injector*	0.15/ 0.30 mg	2	Gray/Red	No (user must recap)	Single pack without trainer	Same as above

EAIs are emergency use products that present specific concerns regarding substitutability

21. Substitutability generally refers to the exchange of one drug for another without any expected difference in clinical effect or safety profile. If Drug X is substitutable for Drug Y, for example, a patient formerly prescribed Drug X may be given Drug Y instead without an expected difference in clinical effect or safety profile.

22. As reflected by their BX-rating, the distinct currently-marketed EAIs are not substitutable.

23. Specifically, EAIs are emergency use products administered by patients or caregivers on an irregular basis and then only in high-stress, emergency situations.

24. It is accordingly essential to patient and product safety that patients and caregivers be instructed on, and become practiced in, the use of their prescribed EAI.

25. To this end, in recognition of the vital importance of patient and caregiver familiarity with his or her prescribed EAI, Mylan Specialty packages every EpiPen 2-Pak® and EpiPen Jr. 2-Pak® with a training device to enable patients, caregivers, and other users to practice the proper administration technique with the product.

26. Mylan Specialty is continually assessing ways to improve user education and reinforce the proper use of its product and has accordingly developed several useful resources, including a training DVD, a smartphone app, and an informative product website, among others.

27. With instruction and practice, use of an EAI should become second-nature.

28. Because each of the distinct currently-marketed EAIs is visually and physically different, and presents distinct user operating principles, substitution of one EAI for another presents a distinct concern for patient safety: that a patient or caregiver will not receive instruction and retaining on the newly-prescribed EAI and will accordingly fail to properly administer the product during an emergency situation.

29. The FDA has noted its own concerns regarding product substitution for EAIs, cautioning that "it is particularly important to ensure that patients in an emergency situation can use the product safely and effectively in accordance with instructions provided for [a product] without additional physician intervention or retraining prior to use" of a different product. Letter

from Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Thomas K. Rogers, III, Executive Vice President, Regulatory Affairs, King Pharmaceuticals, Inc., Dkt. Nos. FDA-2007-P0128 and FDA-2009-P0040 (July 29, 2009) (on file with Affiant).

30. In short, substitution of one EAI for another places patients at risk for product misuse at the time when proper administration is essential: emergency treatment of life-threatening anaphylaxis. And, product misuse can result in the delayed or failed administration of epinephrine, which is associated with negative health outcomes.

EpiPen®, Auvi-Q®, and the PDL

31. Since its introduction, EpiPen® has been reimbursable under the West Virginia Medicaid Program without prior authorization.

32. I attended the regularly-scheduled October 22, 2014, meeting of the Pharmaceuticals and Therapeutics Committee (the "P&T Committee"), which is responsible for recommending revisions to the preferred drug list ("PDL"). During its October 22, 2014, meeting, the P&T Committee considered making Auvi-Q® the preferred EAI for West Virginia Medicaid recipients and making EpiPen® reimbursable only with prior authorization, but tabled a motion to do so.

33. I attended the regularly-scheduled February 28, 2015, meeting of the West Virginia Drug Utilization Review Committee ("DUR Committee") at which the DUR Committee proposed language for the prior authorization for the non-preferred products, EpiPen® and EpiPen Jr.®. At this meeting, I was informed of the development of a letter by two doctors on the P&T Committee to West Virginia medical professionals advising them of the substitution of Auvi-Q® for EpiPen® in the preferred category of the EAI therapeutic class. I was further

informed that this letter was sent to West Virginia medical professionals in advance of the P&T Committee's January 28, 2015, meeting at which the substitution of Auvi-Q® for EpiPen® in the preferred category of the EAI therapeutic class was formally approved.

34. The revisions to the PDL adopted on January 28, 2015, will be effective April 1, 2015, at which time Auvi-Q® will be the preferred EAI for West Virginia Medicaid recipients and EpiPen® will be reimbursable only with prior authorization.

35. Since the regularly-scheduled January 28, 2015, meeting of the P&T Committee, I have learned that the Bureau for Medical Services ("BMS"), which oversees the P&T Committee, has been taking prior to January 28, 2015, to implement the substitution of Auvi-Q® for EpiPen® in the preferred category of the EAI therapeutic class. Specifically, I have learned that BMS sent a newsletter, which predated the P&T Committee's January 28, 2015, meeting, to West Virginia medical professionals advising them of the substitution of Auvi-Q® for EpiPen® in the preferred category of the EAI therapeutic class.

Further, affiant sayeth not.

Margaret J. Wooddell PhD MBA

Taken, subscribed and sworn to before me this 24 day of March, 2015.

My commission expires: September 18, 2017

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Valerie G. Eckert, Notary Public
Cecil Twp., Washington County
My Commission Expires Sept. 18, 2017
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

Notary Public
Valerie G. Eckert

7122149

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. CIVIL ACTION NO. _____

KAREN L. BOWLING, Secretary
of the West Virginia Department
of Health and Human Resources,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S
MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT C

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. **CIVIL ACTION NO. _____**

KAREN L. BOWLING, Secretary of the West Virginia Department of Health and Human Resources,

Defendant.

AFFIDAVIT OF ROGER D. GRAHAM, JR.

I, Roger Graham, being duly sworn, do depose and say as follows:

1. I am above the age of eighteen years and not subject to any legal disabilities. I make the following statements based on my personal knowledge, upon information provided to me by Mylan Specialty employees, and upon review of documents and information maintained by my employer, Mylan Specialty L.P. ("Mylan Specialty") in the regular course of its business.

2. I am employed as President, Mylan Specialty and have been in that position since June 2013. In my current position, I am responsible for leading Mylan Specialty's businesses, including its EpiPen® and EpiPen Jr.® epinephrine auto-injectors (together, "EpiPen®").

3. I am also familiar with Mylan Specialty's participation in various Medicaid pharmacy programs across the United States, including Mylan Specialty's participation in the West Virginia's Medicaid Pharmacy Program.

EpiPen®, Market Reputation, and Product Safety

4. Mylan Specialty and its parent, Mylan Inc., take patient safety, awareness, preparedness, and access extraordinarily seriously and are proud of their accomplishments in these regards.

5. For example, in recognition of the vital importance of patient and caregiver familiarity with his or her prescribed epinephrine auto-injector ("EAI"), Mylan Specialty packages every EpiPen 2-Pak® and EpiPen Jr. 2-Pak® with a training device to enable patients, caregivers, and other users to practice the proper administration technique with the product.

6. Mylan Specialty is continually assessing ways to improve user education and reinforce the proper use of its product and has accordingly developed several useful resources, including a training DVD, a smartphone app, and an informative product website, among others.

7. Another safety and public-service effort that Mylan Specialty has undertaken is the EpiPen4Schools® program, which has provided free EpiPen® auto-injectors and training on their use to more than 53,000 schools nationwide, including more than 250 schools in West Virginia.

8. EpiPen's® record of safety is reflected in the extent to which it is trusted by patients and medical professionals.

9. Nationally, approximately 9 of every 10 scripts for an epinephrine auto-injector ("EAI") are written for EpiPen®, and more than 60 million EpiPen® auto-injectors have been sold in the United States since its introduction.

10. In West Virginia, nearly 22,000 total prescriptions for EpiPen® were written in 2014, representing a substantial portion of the prescribed EAIs for that period. Included in that

figure are more than 7,000 EpiPen® prescriptions written for West Virginia Medicaid recipients, representing even more significant Medicaid market share.

EpiPen®, Market Reputation, and Preferred Drug Lists

11. If EpiPen® is removed from the "preferred" category of the EAI therapeutic class on the West Virginia preferred drug list, I believe that Mylan Specialty will experience harm to its reputation and loss of goodwill among patients and medical professionals. Among other things, I believe that at least some patients and medical professionals will transfer the anger and frustration resulting from this change to Mylan Specialty or EpiPen®.

12. Additionally, if EpiPen® is removed from the "preferred" category of the EAI therapeutic class on the West Virginia preferred drug list, I believe that some medical professionals, absent sufficient explanation to the contrary, will erroneously presume that its replacement in the "preferred" category, Auvi-Q®, is safer or more effective than EpiPen®. This presumption would result in substantial harm to Mylan Specialty's reputation and goodwill.

EpiPen®, Market Share, and Preferred Drug Lists

13. If EpiPen® is removed from the "preferred" category of the EAI therapeutic class on the West Virginia preferred drug list, I believe that EpiPen will lose market share among West Virginia Medicaid recipients. I further believe that EpiPen® will lose market share among other West Virginia users of EAIs as a result of changes to EpiPen's® status on the West Virginia preferred drug list.

14. I believe that decreases in EpiPen's® Medicaid market share, as well as decreases in market share among other West Virginia users of EAIs, will cause Mylan Specialty to incur losses in net revenue from its West Virginia sales.

15. Additionally, even if EpiPen's® removal from the preferred category in the EAI therapeutic class on the West Virginia preferred drug list is later voided or enjoined by Court Order, Mylan Specialty will face significant difficulties in recovering lost market share.

16. As emergency use products, EAIs such as EpiPen® are used irregularly and have long shelf lives. As a consequence, it may be months or years before a person switched from EpiPen® returns to his or her medical provider for a new prescription and Mylan Specialty is even offered the opportunity to recover its market share. More significantly, EpiPen® has no currently-marketed therapeutic equivalents and, once patients are retrained from EpiPen® on a new EAI, most medical professionals will be loath to switch them back to EpiPen®; as distinct products with distinct user operating principles, switching a patient from one EAI to another risks confusing ingrained behaviors in the product's administration and places the patient at risk during emergency situations.

Further, affiant sayeth not.

Roger D. Graham, Jr.

Taken, subscribed and sworn to before me this 24 day of March, 2015.

My commission expires: September 18, 2017

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Valerie G. Eckert, Notary Public
Cecil Twp., Washington County
My Commission Expires Sept. 18, 2017
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

Notary Public
Valerie G. Eckert

7124804

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. CIVIL ACTION NO. _____

KAREN L. BOWLING, Secretary of the West Virginia Department of Health and Human Resources,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT D

Cunningham, Vicki M

From: Thomas Letizia <Thomas.Letizia@mylan.com>
Sent: Tuesday, November 11, 2014 3:22 PM
To: Cunningham, Vicki M
Subject: FW: October P&T Committee Question

Hi Vickie,

Just wanted to follow up on the below to make sure you have the more recent offer and if you might need any other information from me for EpiPen® Auto-Injector.

Thanks so much and have a great day!

Tom Letizia
Regional Account Manager
Managed Markets
Mylan Specialty L.P.
C: 862-259-1661
E: thomas.letizia@mylan.com

From: Thomas Letizia
Sent: Wednesday, November 05, 2014 4:13 PM
To: Cunningham, Vicki M
Subject: October P&T Committee Question

Hi Vickie,

My name is Tom Letizia and am a Regional Account Manager for Mylan Pharmaceuticals. I recently attended the WV State P&T Committee meeting and just had a few questions in regards to EpiPen® Auto-Injector as the committee decided to table discussions until the 1/28/15 meeting.

First, I wanted to confirm that you received the most recent supplemental rebate offer that we submitted through Goold at the end of September? Also, since the rebate offer was submitted after the Draft PDL was posted on the WV website we were concerned that maybe the most recent pricing was not considered when the pre meeting recommendations were stated at the meeting.

When the committee decided to push the discussion to the next meeting they mention needing more information to review. If there is any additional information I can provide you in regards to EpiPen® Auto-Injector please let me know. We currently have an EpiPen® Auto-Injector Dossier available that I can submit if you feel this would help.

I didn't want to bother you with a phone call if you have 10-15mln tomorrow or Friday it might be easier to have this conversation over the phone. Thanks so much and sorry all the question.

Regards,

Tom Letizia
Regional Account Manager
Managed Markets

Mylan Specialty L.P.
C: 862-259-1661
E: thomas.letizia@mylan.com

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. CIVIL ACTION NO. _____

KAREN L. BOWLING, Secretary
of the West Virginia Department
of Health and Human Resources,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT E

Mylan
Seeing
is believing

Mylan Specialty L.P.
1000 Mylan Boulevard
Canonsburg, PA 15317
Phone 724.514.1800
Web mylanspecialty.com

February 25, 2015

Cabinet Secretary Karen Bowling
West Virginia Department of Health and Human Resources
One Davis Square, Suite 100 East
Charleston, West Virginia 25301

Acting Commissioner Cynthia Beane, MSW, LCSW
West Virginia Bureau for Medical Services
Room 251
350 Capitol Street
Charleston, West Virginia 25301

Dear Secretary Bowling and Commissioner Beane:

On behalf of Mylan Specialty L.P., I am writing to raise important issues of patient safety raised by a proposed change in West Virginia's State Medicaid Preferred Drugs List (PDL) with regard to the preferred epinephrine auto-injector to treat life-threatening allergic reactions, such as anaphylaxis. Recently, a committee in the State's Bureau for Medical Services adopted a proposal to substitute Mylan Specialty's epinephrine auto-injector product, EpiPen®, in the PDL with a new product, Auvi-Q®. Significantly, however, the United States Food and Drug Administration ("FDA") has determined that Auvi-Q® is "BX" rated with EpiPen®, which means the FDA considers Auvi-Q® **NOT** to be therapeutically equivalent to EpiPen® and has **NOT** affirmatively deemed it safe to substitute. Unlike products that FDA has determined to be "A" rated, meaning that FDA has found both products to be therapeutically equivalent to each other and thus "can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product," a BX rating denotes those products that FDA "consider[s] NOT to be therapeutically equivalent as actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence."[1]

EpiPen® and Auvi-Q® are auto-injector products intended for use in a medical emergency where a patient is suffering from a life-threatening allergic reaction known as anaphylaxis. The World Allergy Organization recognizes anaphylaxis as a hypersensitivity reaction that is rapid in onset and might cause death.[2] If a patient suffering from anaphylaxis does not rapidly receive treatment (sometimes within a matter of minutes), the outcome can be potentially fatal. Thus, it is critically important that patients and caregivers administering epinephrine treatment in a time of need know how to adequately administer the product. As the FDA has advised, "for a product intended for emergency use by patients without

[1] Approved Drug Products with Therapeutic Equivalence Evaluations (34th Ed.). U.S. Food and Drug Administration available at http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf, at § 1.7.

[2] Simons FE, Ardusso LR, Bilo MB et al. 2012 Update: World Allergy Organization guidelines for the assessment and management of anaphylaxis. *Curr Opin Allergy Clin Immunol* 2012; 12(4):389-399.

professional supervision (such as a prefilled auto-injector indicated for emergency treatment of allergic reactions), it is particularly important to ensure that patients in an emergency situation can use the product safely and effectively in accordance with instructions provided for the [reference product] without additional physician intervention or retraining prior to use."[3]

If a patient or caregiver who has been instructed by a physician and trained to administer EpiPen® is dispensed Auvi-Q® as the proposed change to the state PDL's list would require, the patient or caregiver likely will not know how to use the product, because Auvi-Q® and EpiPen® are unique devices with different methods of administration and different patient instructions. This could have serious safety consequences for the patient if the product cannot be promptly administered in emergency situations in which the need for it arises. The proposed change in the state's PDL list would result in pharmacists automatically substituting Auvi-Q® for patients whose doctors have written a prescription for EpiPen® and who have been trained and grown accustomed to the EpiPen®. So, while this request is not based on any claim of superior efficacy or safety of one type of auto-injector product over another, patients prescribed, accustomed to, and trained to use a particular epinephrine auto-injector may likely discover, in their time of greatest need, that they do not know how to properly use the product their pharmacist has dispensed to them.[4] This can lead to delay or lack of administration of vital medication in an emergency situation.

The proposal apparently is based on anticipated financial savings;[5] however, it is far from clear that savings of any significant magnitude would be realized, because of the concerns associated with the potential fatal outcome if patients and caregivers are delayed in administering treatment, as well as the additional cost of doctor visits that would be required for patient or caregiver training. Consequently, even if there are minimal cost savings, these would be far overshadowed and outweighed by the resulting risks to public safety and access. Accordingly, for the reasons discussed herein, Mylan Specialty respectfully requests that the current proposal to remove EpiPen® auto-injector from the PDL be rejected and that the EpiPen® auto-injector be retained as a preferred product in the PDL.

Anaphylaxis and Epinephrine Auto-Injectors

Epinephrine auto-injectors are ready-to-use self-injectors of epinephrine for the emergency treatment of severe allergic reactions, including potentially fatal anaphylaxis caused by such triggers as food allergies and insect bites. Immediate epinephrine intervention to stop an allergic reaction is essential, as the onset of anaphylaxis is extremely rapid; it can

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[3] Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA, to Mr. Thomas Rogers, Docket Nos. FDA-2007-P-0128 & 2009-P-0040, at 6 (July 29, 2009).

[4] Mylan is not suggesting any safety issue with Auvi-Q®. Indeed, FDA has found Auvi-Q® to be safe and effective. Our point is to convey potential safety concerns that may occur when a patient tries to administer one auto-injector expecting the product to operate the same way as a different one for which he/she trained.

[5] *See* January 28, 2015 Meeting Minutes of the Pharmaceutical and Therapeutics Committee, Department of Health and Human Resources at 3 (noting "the overall savings for the entire class").

progress from exposure to cardiorespiratory arrest in as little as five minutes.[6] Anaphylaxis has been estimated to occur as frequently as in 1 in 20 adults in the U.S., and to result in perhaps as many as 100 deaths annually.[7] In that regard, the failure to inject epinephrine promptly has been identified as the most significant factor contributing to death.[8] The World Health Organization classifies epinephrine as an essential medication for the treatment of anaphylaxis, and all published national guidelines emphasize prompt injection of epinephrine as the only first-line therapy for an acute episode. Moreover, data from a nationwide, comprehensive survey of over 6000 schools participating in the EpiPen4Schools® program during the 2013-2014 academic year, sponsored by Mylan, to help understand anaphylaxis and the importance of access in schools showed that 1 in 10 schools had an anaphylactic event among children and school staff and, more importantly, >20% of the anaphylactic events occurred in students not known by personnel to have a prior history of life-threatening allergies.[9]

Because of the unpredictable circumstances in which the risk of anaphylaxis arises and the need for immediate treatment, epinephrine auto-injectors are most frequently used by patients (including children) and caregivers, and not healthcare professionals. Moreover, these products typically are used on an infrequent and irregular basis, under highly stressful, time-sensitive conditions, where the patient or caregiver must quickly recognize the signs and symptoms of anaphylaxis and execute a successful injection. Because it is essential that a patient or caregiver be familiar with his or her epinephrine auto-injector and able to use it effectively in an emergency, the Food and Drug Administration (FDA) has required each of the currently marketed epinephrine auto-injectors to have patient-directed instructions for use, to be made available with a trainer device and to direct prescribers to instruct patients and caregivers in the use of the product.[10] Furthermore, the FDA has noted that for patients who have been trained in the use of a particular epinephrine auto-injector, switching to a different device may increase the likelihood of confusion during administration of epinephrine in response to anaphylaxis.[11]

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[6] *See, e.g.,* Pumphrey RSH, lessons for management of anaphylaxis from a study of fatal reactions, Clin Exp Allergy. (2000) 30:1144-1150, Summary, Table 3.

[7] *See, e.g.,* R. Wood *et al.*, Anaphylaxis in America: The prevalence and characteristics of anaphylaxis in the United States, 133 J. ALLERGY CLIN. IMMUNOL. 461, 467 (Feb. 2014); L. Ma *et al.*, Case fatality and population mortality associated with anaphylaxis in the United States, 133 J. ALLERGY CLIN. IMMUNOL. 1075, 1075 (Apr. 2014).

[8] *See, e.g.,* Bock *et al.*, "Fatalities due to anaphylactic reactions to food," *J. Allergy Clin. Immunol.* 2001; 107:191-193.

[9] Data on File, Mylan Specialty L.P.

[10] *See, e.g.,* EpiPen® Prescribing Information, *Patient Counseling Information* (§ 17); Auvi-Q® Prescribing Information, *Patient Counseling Information* (§ 17).

[11] July 29, 2009 Letter from Janet Woodcock, MD (FDA) to Thomas Rogers (King Pharmaceuticals), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2009-P-0040-0006 (King Petition Response); May 27, 2010 Letter from Woodcock to Sunil Mehra (Dey Pharma), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2009-P-0578-0007 (Dey Petition Response). Dey was renamed Mylan Specialty in 2012 and is a subsidiary of Mylan Inc. The Dey petition was specifically about proposed generic versions of EpiPen®; *see, e.g.,* Ram FSF, Hoare K, Auroll B, Hoare S. Epinephrine self-administration in anaphylaxis emergency: comparison of commonly available auto-injectors. J of Asthma & Allergy Educators 2012;3:1.

Proposed Change to the PDL

Marketed since the 1980's, EpiPen® has a decades-long history of safe and effective use. It is by far the most widely prescribed epinephrine auto-injector in the U.S., and has been a preferred product on the West Virginia PDL for years. Its status as a preferred product has ensured that those West Virginia citizens who need and rely on EpiPen® have unfettered access to the product without the need for prior authorization. As a result, the vast majority of West Virginia patients (including but not limited to those covered by Medicaid) have been trained on, and are familiar with, EpiPen®. Over the last year alone, more than 7,000 prescriptions for EpiPen® auto-injectors were written for West Virginia Medicaid patients.[12] Despite this, the Pharmaceutical and Therapeutics Committee of the Bureau for Medical Services (P&T Committee) on January 28, 2015, adopted a recommendation from its vendor, Magellan Health Services, Inc., that EpiPen® be substituted with a new product, Auvi-Q®, as the preferred epinephrine auto-injector on the State's PDL.

Preferred product recommendations generally are based on clinical and financial comparisons between products in the same therapeutic class.[13] Clinical safety and efficacy data are analyzed to comparatively evaluate products in a given therapeutic class, and a financial analysis is performed that incorporates State utilization data and net drug costs from the manufacturers. Although a simple comparison of each product's safety, effectiveness and cost may be adequate for most drugs (such as tablets and capsules containing the same active ingredient), that is not the case with epinephrine auto-injectors, where the product is complex and delay or failure in administration can be fatal. Accordingly, any decision as to moving patients from the EpiPen® to Auvi-Q® must take into account the potential impact on a patient or caregiver in an emergency having to use a device with which he or she is not familiar, as well as the costs associated with patient/caregiver training on the new device.

EpiPen® Auto-Injector

Because it is intended for emergency use by patients and caregivers in stressful (and potentially fatal) situations, EpiPen® incorporates a number of characteristics to allow users, and notably the vast majority of West Virginians who use epinephrine auto-injectors, to become familiar and comfortable with the product and its operation, so that they can use the product safely and effectively. Among other things:

- The product labeling includes a Patient Insert with easy-to-read instructions for use.

- The Prescribing Information directs healthcare providers to "review the patient instructions and operation of EpiPen® . . . in detail, with the patient or caregiver," and provides that "[p]atients and/or caregivers should be instructed in the appropriate use of EpiPen® Auto-Injector and EpiPen Jr.®"

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[12] IMS Plan Track Data (TRx 12 months Dec 2013 – Nov 2014).

[13] Bureau for Medical Services, Frequently Asked Questions regarding the West Virginia Medicaid Preferred Drug List (PDL) (Revised 10/2014).

- The Patient Insert states that "[y]our healthcare provider will show you how to safely use the EpiPen® or EpiPen Jr.® Auto-Injector" and instructs patients to "[u]se your EpiPen® or EpiPen Jr.® exactly as your healthcare provider tells you to use it."

- The product is packaged with a trainer device and related instructions so patients and caregivers can practice using the product. As stated in the Prescribing Information, "[p]atients and/or caregivers should be instructed to use the Trainer to familiarize themselves with the use of the EpiPen® auto-injector in an allergic emergency."

- There is a training DVD on how to use the EpiPen® auto-injector.

- Healthcare professionals receive hands-on training, so they can better assist patients and caregivers.

Moreover, the device itself is designed to be intuitive to use. Its cylindrical shape fits easily in the hand, and patients need only (1) remove the safety cap to enable injection, and (2) inject the drug by swinging the device and jabbing it into the thigh.

Differences Between EpiPen® and Auvi-Q®

A corollary to the importance of patient and caregiver familiarity with the prescribed epinephrine auto-injector is the significance of differences between auto-injectors when patients are switched from one product to another. FDA addressed this issue directly in its responses to citizen petitions from King Pharmaceuticals and Dey Pharma regarding approval of proposed generic auto-injectors.[14] In those responses the agency explained that, particularly with regard to auto-injectors intended for emergency use (like epinephrine auto-injectors), it is imperative that patients and caregivers trained in, and familiar with, one product be able to safely and effectively use the substituted product. This requires careful scrutiny of any differences in design and operating principles, because in the context of proposed generic products, FDA has said that patients and caregivers must be able to use the generic without any training on the new product. Auvi-Q® is not a generic EpiPen®, and the products differ in significant ways that have important safety implications for patients.

The removal of EpiPen® as a preferred epinephrine auto-injector listed on the State's PDL likely will mean that the vast majority of West Virginia Medicaid beneficiaries will be switched from the EpiPen®, with which they are familiar, to the Auvi-Q®. With this in mind, the differences between the two products in terms of design and operation are important. They include the following:

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[14] July 29, 2009 Letter from Janet Woodcock, MD (FDA) to Thomas Rogers (King Pharmaceuticals), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2009-P-0040-0006 (King Petition Response); May 27, 2010 Letter from Woodcock to Sunil Mehra (Dey Pharma), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2009-P-0578-0007 (Dey Petition Response).

EpiPen®

Auvi-Q®

Physical Design

- EpiPen® is a cylinder, meant to be gripped with the fingers and thumb of one hand wrapped around it.
- Auvi-Q® is a rectangular cube that is held in the palm, with fingers wrapped around and the thumb on the top of the device.

Preparation

- EpiPen® is removed from its carrier tube by holding the tube in one hand, flipping open the top with the thumb, and sliding the device out of the tube.
- Auvi-Q® is removed from its outer case by holding the end of the device in the thumb and forefinger of one hand, grasping the case with the other thumb and forefinger, and pulling the device and case apart.

Removing the Safety

- EpiPen® has a safety cap on the non-needle end of the device that is pulled up and off. Users are instructed to never put their thumb, fingers or hand over the needle end of the device, which is orange in color.[15]
- Auvi-Q® has a red safety guard over the needle end of the device that is pulled down and off.

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[15] The Patient Information states, "**Caution: Never put your thumb, fingers, or hand over the orange tip. Never press or push the orange tip with your thumb, fingers, or hand.** The needle comes out of the orange tip." (emphasis in the original)

Injection

- The user swings the EpiPen® and firmly pushes the tip against the middle of the outer thigh until a click is heard, holds the device in place at a 90° angle for 10 seconds, removes the device, and massages the injection area for 10 seconds.

- Auvi-Q® is injected by placing the device against the thigh, pressing firmly until a click and hiss is heard, and holding in place for 5 seconds.

Reflecting the differences between the devices, FDA has rated them as "BX" in the Orange Book, which means the agency does not consider Auvi-Q® to be therapeutically equivalent to, or interchangeable with, EpiPen®. By rating the devices with a "BX" therapeutic equivalence rating, the FDA has determined that there are insufficient data to permit a determination that these epinephrine auto-injectors are therapeutically equivalent and safe to substitute for one another. As a result, the substitution of a different auto injector for EpiPen®, when the patient has already been trained on EpiPen®, is inappropriate, as it could have serious safety consequences for a patient.

Implications for Patient Safety and West Virginia Medicaid Costs

These differences mean that when a patient who has been prescribed EpiPen® (which is the vast majority of West Virginia Medicaid beneficiaries who are prescribed an epinephrine auto-injector) is switched to Auvi-Q®, the patient and/or caregivers will need training on the new device in order to be able to use the product safely and effectively. This is, of course, consistent with the Auvi-Q® labeling, which directs the healthcare provider to "review the patient instructions and operation of Auvi-Q®, in detail, with the patient or caregiver."[16] This, in turn, will require a visit to the prescribing healthcare practitioner that otherwise would not be necessary. The reimbursement costs associated with that visit must be accounted for in calculating the financial implications of replacing EpiPen® with Auvi-Q® on the PDL. In addition, there are indirect costs that must be considered, such as the patient and/or caregiver's lost time from work to attend an appointment to receive training from a healthcare professional. In fact, the burdens may simply cause some patients or caregivers to forego the training, which could lead to disastrous results, if a patient or caregiver facing a life-threatening emergency is forced to use an unfamiliar device.

Moreover, even with training, there are important safety considerations at stake. The goal of training is for patients and caregivers to be able to use the device instinctively in an emergency, when they are under stress and immediate action is required. With that in mind, when faced with such an emergency, some patients and caregivers with years of experience and familiarity with the EpiPen® may have difficulty "unlearning" long-ingrained procedures, remembering the new instructions, or may otherwise not quickly and effectively operate the Auvi-Q®. In light of the potentially fatal effects of anaphylaxis, any delay or incompleteness (let alone failure) in administering epinephrine can have life-threatening consequences.

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[16] Auvi-Q® Prescribing Information, *Patient Counseling Information* (§ 17).

The implications of the proposed change are compounded by the widespread access to EpiPen® that West Virginians have enjoyed for years. EpiPen® has been on the market for more than 25 years and accounts for almost 90% of epinephrine auto-injector prescriptions nationwide. If the proposal is accepted, West Virginia would only be one of two states in the United States to not include EpiPen® in their preferred drug list in 2015. Moreover, Mylan Specialty has made a significant investment in providing free access and training to West Virginia communities. By way of example, as part of the EpiPen4Schools® program, Mylan Specialty has provided free EpiPen® auto-injectors to approximately one-third of the schools in West Virginia and sponsored training sessions for West Virginia school nurses. We make these efforts nationwide, but feel a special connection to patients, caregivers, and healthcare professionals in West Virginia, where Mylan was founded and has over 3,000 employees.

Conclusion

Epinephrine auto-injectors are complex drug-device combination products intended for infrequent use by patients and caregivers in potentially life-threatening emergency situations. In that regard, epinephrine auto-injectors are different from most drugs on the PDL, and the decision about which product is preferred requires consideration of issues that do not arise with most other drugs on the PDL. The record of the proceedings to date indicates that the proposed change has been driven by perceived financial benefits. For the reasons discussed in this letter, however, we believe the purported cost savings are not what they may have been thought to be, and there are important patient safety issues that have not been adequately considered, especially where a delay or failure to appropriately administer epinephrine could be a matter of life and death.

The long-standing designation of EpiPen® as a preferred drug on the PDL has served West Virginians well. Accordingly, we respectfully urge that the proposal to remove EpiPen® be rejected and that it remains as a preferred drug on the PDL.

Thank you for your attention to this matter. Please contact me if we can provide additional information.

Respectfully submitted,

Rafael Muniz, MD
Vice President, Global Medical Affairs

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. CIVIL ACTION NO. _____

KAREN L. BOWLING, Secretary
of the West Virginia Department
of Health and Human Resources,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT F

Allergy & Asthma NETWORK

8229 Boone Boulevard, Suite 260, Vienna VA 22182 · 800.878.4403 · www.aanma.org

February 23, 2015

Mr. Brian M. Thompson, MS, PharmD
Drug Utilization Review Coordinator

Ms. Cynthia Beane, MSW, LCSW
Acting Commissione

To Whom It May Concern:

Allergy & Asthma Network is the leading national nonprofit dedicated to ending needless death and suffering due to asthma, allergies and related conditions through outreach, education, advocacy and research. Since 1985 we have been engaging, educating and empowering people to win over life-threatening allergies and anaphylaxis.

Due to this passion, we are writing to respectfully request EpiPen Auto-injector maintain its current preferred status on West Virginia Medicaid formulary in order to prevent any barriers to access in a life-threatening circumstance.

The truth is approximately **700,000** West Virginians are at risk for anaphylaxis, a severe life-threatening allergic reaction. The truth is greater than 90% of those at risk should be armed with an epinephrine autoinjector that they are familiar with and are prepared to use when the need arises. The truth is at least 1-2 people die from anaphylaxis each and every day in the US and the most common reason is delay in administration of epinephrine. The truth is the manufacturer of EpiPen has donated millions of dollars and free product to help ensure no further lives are lost.

Our question is simple...is the state of West Virginia or the P&T committee of West Virginia Medicaid prepared to face the mother who has lost her child because of this decision to limit access to the only product that child has ever been trained to use in order to save his life?

We understand patient and physician choice of treatment is a challenging one that is often ripe with complex considerations....accurate medical diagnosis, access to care, education level, ability to self-administer or self-advocate, cost, coverage, and potential side effects just to name a few. By excluding EpiPen from covered status, many patients will be forced to seek unscheduled office visits, ER visits, and hospitalizations due to the lack of familiarity and understanding of the alternate device. In fact, we believe the patient population most impacted by this decision is the one often at highest risk and the most underserved.

Rarely do we feel the need to voice our opinion on formulary decisions; however, in this instance we could not sit idly by and allow this to move forward without rallying our community and imploring you to reconsider your position. The organizations listed below join our efforts in ensuring **ALL** patients at risk for life-threatening allergies and anaphylaxis have access to the medication that has saved millions of lives for more than 25 years.

Respectfully Submitted,

Tonya A. Winders

Tonya A. Winders, MBA
President & CEO
Allergy & Asthma Network

Collectively supported by:

ACAAI American College of Allergy, Asthma & Immunology

allergist

Anaphylaxis Community Experts

MEDICAL HOME CHAPTER CHAMPIONS

ALAA American Latex Allergy Association

FAACT Food Allergy & Anaphylaxis Connection Team

Allergy & Asthma NETWORK

8229 Boone Boulevard, Suite 260, Vienna VA 22182 • 800.878.4403 • *www.aanma.org*

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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT G

FARE
Food Allergy Research & Education

24 February 2015

Karen L. Bowling
Cabinet Secretary
West Virginia Department of Health and Human Resources
One Davis Square, Suite 100 East
Charleston, West Virginia 25301
Phone: (304) 558-0684
Fax: (304) 558-1130

Dear Secretary Bowling:

FARE is the leading national organization supporting individuals with food allergies. There is no effective treatment for this life threatening condition, and these patients are dependent on injectable epinephrine to treat life-threatening allergic reactions. Because these devices require unique training and have both technical and aesthetic differences, we support patients having equal access to all of these devices.

We appreciate your consideration of this issue.

Sincerely,

James R. Baker, Jr. MD
CEO
FARE

National Headquarters
7925 Jones Branch Drive
Suite 1100
McLean, VA 22102
800-929-4040 phone
703-691-2713 fax
www.foodallergy.org

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

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KAREN L. BOWLING, Secretary
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MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT H

Cunningham, Vicki M

From: Bandali, Nina <NBandali@magellanhealth.com>
Sent: Friday, December 05, 2014 4:04 PM
To: Cunningham, Vicki M
Subject: RE: EpiPen Supplemental Rebate Agreement

Sorry, one other thing, there is a such a disparity in pricing between Auvi-Q and Epipen [redacted] when you look at the cost net of rebates. So can GHS play that up with Mylan and let them know that they are way out of line with their pricing?

From: Bandali, Nina
Sent: Friday, December 05, 2014 4:02 PM
To: 'Cunningham, Vicki M'
Subject: RE: EpiPen Supplemental Rebate Agreement

Yes, I am. 51% is the break-even and that is a lot of market share to move esp. with such strong brand recognition. It concerns me that this will impact kids and that means everyone would have to be taken off a product that they have known for so long and retrained (granted training shouldn't be relatively easy). My other concern is that no other state has Auvi-Q in a sole preferred position. Of all of our states, only 2 states have Auvi-Q in a co-preferred position. What are other SSDC states doing?

From: Cunningham, Vicki M [mailto:Vicki.M.Cunningham@wv.gov]
Sent: Friday, December 05, 2014 3:58 PM
To: Bandali, Nina
Subject: RE: EpiPen Supplemental Rebate Agreement

I think that was their enhanced offer, but I can check. Why EpiPen? Are you concerned about us shifting market share?
Vicki

Vicki.M.Cunningham, R.Ph.
Director of Pharmacy Services
Bureau for Medical Services
Phone 304-356-4857
FAX 304-558-1542
e-mail Vicki.M.Cunningham@wv.gov

From: Bandali, Nina [mailto:NBandali@magellanhealth.com]
Sent: Friday, December 05, 2014 3:41 PM
To: Cunningham, Vicki M
Subject: RE: EpiPen Supplemental Rebate Agreement

Thanks, any way for GHS to negotiate a better offer for Epipen or is that closed all together? I'm heading towards the recommendation that Steve Lyles had in regards to this class but a better offer would make me feel better.

From: Cunningham, Vicki M [mailto:Vicki.M.Cunningham@wv.gov]
Sent: Friday, December 05, 2014 3:22 PM
To: Bandali, Nina
Subject: FW: EpiPen Supplemental Rebate Agreement

FYI

Vicki.M.Cunningham, R.Ph.
Director of Pharmacy Services
Bureau for Medical Services
Phone 304-356-4857
FAX 304-558-1542
e-mail Vicki.M.Cunningham@wv.gov

From: Thomas Letizia [mailto:Thomas.Letizia@mylan.com]
Sent: Thursday, December 04, 2014 9:30 AM
To: Cunningham, Vicki M
Subject: RE: EpiPen Supplemental Rebate Agreement

Thanks for the clarification Vickie! Yes, this is acceptable to Mylan. The contracts are currently being routed for completion and signatures and you should have them by the stated deadline.

Please let me know if there is any other information you may need that Mylan can provide to help make the final decision at the January meeting.

Regards,

Tom Letizia

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. CIVIL ACTION NO. _____

KAREN L. BOWLING, Secretary
of the West Virginia Department
of Health and Human Resources,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S
MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT I

DEPARTMENT OF HEALTH & HUMAN SERVICES

IIA 305
(2007-P-0128)

JUL 29 2009

Food and Drug Administration
Rockville MD 20857

0403 9 JUL 31 P1:34

Thomas K. Rogers, III
Executive Vice President, Regulatory Affairs
King Pharmaceuticals, Inc.
501 Fifth Street
Bristol, TN 37620

Re: Docket No. FDA-2007-P-0128
Docket No. FDA-2009-P-0040

Dear Mr. Rogers:

This is a consolidated response to your two citizen petitions requesting that the Food and Drug Administration (FDA or Agency) take various actions with regard to approving drug products containing auto-injectors.[1] The first petition, dated September 26, 2007, (Petition 1)[2] requests that the Agency:

1. Decline to approve or stay the approval of any abbreviated new drug application (ANDA) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act) that references a drug product containing an auto-injector as the listed drug, unless it has been demonstrated that the proposed auto-injector is, as described in the petition, the "same" as the auto-injector in the reference listed drug (RLD);

2. Refuse to designate any drug product containing an auto-injector approved under sections 505(b) or 505(j) of the Act as therapeutically equivalent to an RLD containing an auto-injector, unless, as described in Petition 1, it has been demonstrated that the auto-injector is pharmaceutically equivalent to, bioequivalent to, and has the same labeling as the auto-injector contained in the RLD; and

3. Require that sponsors of new drug products containing auto-injectors conduct appropriate clinical studies in patients under the conditions for which the auto-injector is indicated if: (1) sponsors seek approval for a drug product containing an auto-injector under section 505(b)(2) or under a suitability petition; and (2) the auto-injector is not the "same" as the auto-injector contained in the RLD.

The second petition, dated January 29, 2009 (Petition 2), requests that the Agency:

[1] In this document, we will at times use the term used in the incoming citizen petitions, "drug product containing an auto-injector," for ease of comprehension and reciprocal consistency. At other times, we will use the terminology, "combination product consisting of an auto-injector constituent part and a drug constituent part" or other similar terminology. No difference in meaning is intended.

[2] This citizen petition was originally assigned docket number 2007P-0361/CP1. The number was changed to FDA-2007-P-0128 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

FDA-2009-P-0040

PPAD

1. Confirm that it will only approve ANDAs for sumatriptan succinate injection containing an auto-injector when the proposed drug product contains an auto-injector that is identical to the reference product's auto injector in performance, physical characteristics, and labeled instructions; and

2. In conjunction with the approval of any injectable sumatriptan ANDA, clarify drug nomenclature to ensure consistent identification of dosage form, route of administration, and strength for all drug products containing sumatriptan.

We have carefully reviewed the petitions and the comments submitted. For the reasons stated below, we grant your requests in part, and deny them in part.

I. BACKGROUND

Although Petition 1 is not product-specific, Petition 2 refers explicitly to sumatriptan succinate. Imitrex (sumatriptan succinate) Injection, a selective 5-hydroxytryptamine receptor subtype agonist, was approved by FDA on December 28, 1992, for the acute treatment of migraine attacks with or without aura and for the acute treatment of cluster headache episodes. Additional dosage forms (tablet and nasal spray) were approved in 1995 and 1997, respectively. The Imitrex STATdose system, which includes an auto-injector, was approved by FDA in 1996.

A. Summary of Legal and Regulatory Framework for ANDAs and 505(b)(2) Applications

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments) created the statutory provisions governing ANDAs and 505(b)(2) applications. The Hatch-Waxman Amendments reflect Congress's attempt to balance the need to encourage innovation with the desire to speed the availability of lower-cost alternatives to approved drugs. With passage of the Hatch-Waxman Amendments, the Act describes different routes for obtaining approval of two broad categories of drug applications: (1) NDAs, for which the requirements are set out in section 505(b) and (c) of the Act, and (2) ANDAs, for which the requirements are set out in section 505(j). These categories can be further subdivided as follows:

- Stand-alone NDA — an application that contains full reports of investigations of safety and effectiveness that were conducted by or for the applicant or for which the applicant has a right of reference (section 505(b)(1)).

- 505(b)(2) application — an application that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (section 505(b)(2)).

- ANDA — an application for a duplicate of a previously approved drug that contains information to show that the proposed product contains the same active ingredient(s), dosage form, strength, route of administration, labeling, quality, performance characteristics, and conditions of use, among other things, as a previously approved product, and for which clinical studies are not necessary to show safety and effectiveness (section 505(j)).

- Petitioned ANDA — an application for a drug that differs from a previously approved drug product in dosage form, route of administration, strength, or active ingredient (in a product with more than one active ingredient), for which FDA has determined, in response to a *suitability petition* submitted under section 505(j)(2)(C), that clinical studies are not necessary to show safety and effectiveness (section 505(j)). (See section 505(j)(2)(A), (j)(2)(C), and (j)(4) of the Act and 21 CFR 314.93.)

To obtain approval for an ANDA, an ANDA applicant is not required to submit evidence to establish the clinical safety and effectiveness of the drug product; instead, an ANDA relies on FDA's previous finding that the reference listed drug (RLD) is safe and effective. Under the Hatch-Waxman Amendments, to rely on a previous finding of safety and effectiveness, an ANDA applicant must demonstrate, among other things, that its proposed drug product is bioequivalent to the RLD. In addition, a drug product described in an ANDA (other than a petitioned ANDA) generally must contain the same active ingredient, conditions of use, route of administration, dosage form, strength, and (with certain permissible differences) labeling as the RLD (see, e.g., 21 CFR 314.94(a)(4)-(a)(8)). An ANDA applicant also must demonstrate that its proposed drug product meets approval requirements relating to the chemistry, manufacturing, and controls for the drug product. An ANDA is generally not required to be the same as the listed drug it references in certain other respects (e.g., it can differ in inactive ingredients or container closure system). However, where differences in these aspects of the products are significant enough that they require clinical studies to assure FDA of safety or effectiveness or necessitate such significant labeling differences that the labeling is no longer "the same" as the RLD's, FDA will deny an ANDA approval.

FDA publishes (previously in paper copy and now electronically on its Web site), *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book). Among other things, the Orange Book provides FDA's recommendations regarding whether products that are pharmaceutically equivalent[3] are therapeutically equivalent, and therefore, substitutable. Drug products that meet the approval requirements under section 505(j) in that they are, among other things, bioequivalent to and have the same active ingredient, conditions of use, strength, dosage form, route of administration, and

[3] Pharmaceutically equivalent drug products have the same dosage form, strength, and route of administration, and contain the same amounts of the same active drug ingredient and meet the same compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates. They do not necessarily contain the same inactive ingredients and may also differ in characteristics such as shape, scoring, release mechanism, and, within certain narrow limits, labeling (see 21 CFR 320.1 and the Orange Book, Introduction at p. vi et seq.).

labeling (with certain permissible differences due to difference in manufacturer) as the RLD will be considered by FDA to be therapeutically equivalent to the RLD. If FDA determines that drugs are therapeutically equivalent to one another, it gives them an "A" therapeutic equivalence rating in the Orange Book. An "A" rating reflects FDA's judgment that the products generally may be substituted for each other without physician intervention with the expectation that the substituted product will produce the same clinical effect and safety profile as the RLD when used for the labeled uses. [4]

Where products with the same active ingredient, strength, dosage form, and route of administration have differences in packaging configurations, inactive ingredients, or other differences that have significant therapeutic implications or otherwise require additional clinical studies to establish safety and effectiveness, however, the products will not meet the standards for ANDA approval. In some such cases, bioequivalent and pharmaceutically equivalent products have not been considered therapeutic equivalents and are not given an "A" therapeutic equivalence rating (see the Orange Book, Introduction at p. xv, noting that oral contraceptives packaged in 21-day packages without placebos and oral contraceptives packaged in 28-day packages with 7 placebos are not therapeutically equivalent in spite of containing the same amount of the same active ingredient, same dosage form, strength, and route of administration).

Section 505(b)(2) of the Act provides that an application may be submitted under section 505(b)(1) for a drug for which the safety and effectiveness investigations relied upon by the applicant to support approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. A 505(b)(2) application shares characteristics of both an ANDA and a stand-alone NDA. Like a stand-alone NDA, a 505(b)(2) application is submitted under section 505(b)(1) of the Act and approved under section 505(c). As such, it must satisfy the same statutory requirements for safety and effectiveness information as a stand-alone NDA. A 505(b)(2) application is similar to an ANDA as well because it may rely in part on FDA's finding that the listed drug it references (RLD) is safe and effective as evidence in support of the proposed product's own safety and effectiveness. Although an ANDA is generally required to duplicate an innovator product (with a few limited exceptions), a 505(b)(2) application may describe a drug with substantial differences from the listed drug it references. These differences may include, for example, a different active ingredient, new indication, dosage form, strength, formulation, route of administration, or any other change for which clinical studies other than bioavailability or bioequivalence studies are needed to ensure safety or effectiveness of the changed drug product (see 21 CFR 314.54(a); see also the draft guidance for industry entitled *Applications Covered by Section 505(b)(2)*). A 505(b)(2) application that relies on the finding of safety or effectiveness for a listed drug must bridge to the listed drug it references and support any differences from the listed drug it references with appropriate safety and effectiveness information.

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[4] The Orange Book (*Approved Drug Products with Therapeutic Equivalence Evaluations)*, preface to the 29th Edition, pages vii, xiii-xvii, available at: *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf*.

B. Combination Products

Section 503(g)(1) of the Act vests authority in the Secretary of the Department of Health and Human Services[5] to assign an Agency center to regulate products that constitute a combination of a drug, device, or biological product. Section 503(g)(1) further specifies that if the primary mode of action of the combination product is that of a drug, the Agency center charged with premarket review of drugs (i.e., the Center for Drug Evaluation and Research, CDER) shall have primary jurisdiction. Section 503(g)(4)(H) further specifies that "nothing in this paragraph shall be construed to limit the regulatory authority of any agency center." Section 563 of the Act establishes a procedure whereby applicants may request a determination respecting the classification of a product as a drug, biological product, device, or a combination product. The Agency has adopted regulations implementing sections 503(g) and 563 of the Act, codified at 21 CFR part 3. Under the operation of these provisions, a product consisting of an auto-injector prefilled with a parenteral drug will generally be assigned to CDER as the lead center for premarket review in accordance with the drug as the primary mode of action. CDER may consult with CDRH to ensure acceptability of provided information. We note that the subject of your petition ("ANDA drug product containing an auto-injector") meets the definition of a combination product (21 CFR 3.2(e)).

In April 2009, the Agency published a draft guidance document entitled *Draft Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products.*[6] This document includes recommendations regarding the submission of marketing applications seeking approval of combination products consisting of an auto-injector and a drug or biological product.

C. Section 505(q) of the Act

Your second petition, dated January 29, 2009, is subject to section 914 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amended section 505 of the Act (21 U.S.C. 355) by adding new subsection (q). Section 505(q) of the Act applies to certain citizen petitions and petitions for stay of Agency action that request that FDA take any form of action relating to a pending application submitted under section 505(b)(2) or (j) of the Act (21 U.S.C. 355(b)(2) or (j)) and governs the manner in which these petitions are treated. Among other things, section 505(q)(1)(F) of the Act governs the time frame for final Agency action on a petition subject to section 505(q). Under this provision, FDA must take final Agency action on a petition not later than 180 days after the date on which the petition is submitted. The 180-day period is not to be extended for any reason.

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[5] The Secretary has delegated this authority to the Commissioner of Food and Drugs.

[6] See *Federal Register* Notice and request for comments (74 FR 19094, April 27, 2009). Draft guidance document is available at: *http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM147095.pdf*.

II. DISCUSSION

The following sections discuss the petition requests and the grounds for those requests, generally organized around subject matter.

A. Sameness

You ask, in Petition 1, that the Agency not approve any ANDA that references a drug product containing an auto-injector as the listed drug unless it has been demonstrated that the proposed auto-injector is the "same" as the auto-injector in the RLD (Petition 1 at 7). Petition 2 more specifically requests that the Agency only approve any ANDAs for sumatriptan succinate injection containing an auto-injector when the proposed drug product contains an auto-injector that is identical to the reference product's auto injector in performance, physical characteristics, and labeled instructions (Petition 2 at 2).

The Agency's review process for ANDAs for combination products considers whether any difference in materials, design, or operating principles introduces a new risk. This review includes consideration of both risks intrinsic to the new product and risks associated with switching from one product to the other without additional physician intervention or training. This review considers the RLD as a whole and its individual constituent parts.

FDA agrees that when reviewing an ANDA for a combination product that includes an auto-injector constituent part, it must evaluate the auto-injector constituent part of the combination product for which ANDA approval is sought to ensure that its performance characteristics and critical design attributes will result in a product that will perform the same as the RLD. This does not mean, however, that all design features of the auto-injector in the ANDA and its RLD must be exactly the same. Some design differences may be acceptable as long as they do not significantly alter product performance or operating principles and do not result in impermissible differences in labeling.

Thus, FDA determines whether the basic design and operating principles are the same, and whether any minor differences require significant differences in labeling for safe and effective use. For ANDAs for a product with labeling that describes use by patients without physician supervision and further requires training of patients by a physician prior to initial unsupervised use, FDA considers whether patients can be safely switched to a new product without retraining by a physician or health care professional. For an ANDA for a product intended for emergency use by patients without professional supervision (such as a prefilled auto-injector indicated for emergency treatment of allergic reactions), it is particularly important to ensure that patients in an emergency situation can use the product safely and effectively in accordance with instructions provided for the RLD without additional physician intervention or retraining prior to use. A similar standard may be applied to certain products not intended for emergency use, if appropriate.

ANDA applicants, including applicants for ANDAs for sumatriptan auto-injectors, would be required to provide details on attributes such as auto-injector design, materials, operating principles, and comparative performance tests between the auto-injector constituent of the RLD and the auto-injector constituent of the product described in the ANDA. If FDA determines that the auto-injector constituent of a product proposed in an ANDA is not equivalent to the auto-injector constituent of the RLD in terms of performance and critical design, FDA will refuse to approve the ANDA for that product. Similarly, if the labeling is not the same (with the exception of certain permissible differences due to difference in manufacturer), ANDA approval will be denied. Clinical usability or human factor studies may also be required, depending on the indication and the patient population, the nature of the auto-injector design, and differences from the auto-injector constituent part of the RLD, to ensure that the proposed product is safe and effective. If required, such studies are beyond the scope of studies that can be reviewed and approved in an ANDA.

In the case of sumatriptan auto-injectors, we note that individuals experiencing migraines (the indication for which sumatriptan auto-injectors are indicated) may experience varying degrees of mental impairment, and this may affect the usability of an auto-injector, leading to possible errors or misadministration of the product. We further note that the RLD's approved labeling states, "Patients who are advised to self-administer [this product] in medically unsupervised situations should receive instruction on the proper use of the product from the physician or other suitably qualified health care professional prior to doing so for the first time." Thus, in reviewing an ANDA referencing this product, FDA will have to consider whether, given the characteristics of the proposed auto-injector constituent, the product can be safely substituted for the RLD without additional physician intervention or retraining prior to use.

B. Designation of Therapeutic Equivalence

You request that the Agency refuse to designate any drug product containing an auto-injector approved under sections 505(b) or 505(j) of the Act as therapeutically equivalent to an RLD containing an auto-injector, unless, as described in the petitions, it has been demonstrated that the auto-injector is pharmaceutically equivalent to, bioequivalent to, and has the same labeling as the auto-injector contained in the RLD (Petition 1 at 2).

As noted above, drug products are considered to be therapeutic equivalents and will receive an "A" rating in the Orange Book only if they are bioequivalent pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients for the labeled uses. As further noted above, FDA considers the auto-injector constituent part along with the drug constituent part when determining therapeutic equivalence ratings for a drug/auto-injector combination product. These evaluations are undertaken on a case-by-case basis when an ANDA is being reviewed, and thus the Agency cannot provide a more detailed description of what auto-injector characteristics would or would not be acceptable.

C. Need for Clinical Studies

You request that sponsors of new combination products containing auto-injectors be required to conduct clinical studies if approval for a drug product containing an auto-injector is sought under section 505(b)(2) or under a suitability petition, and the auto-injector is not the "same" as the auto-injector contained in the RLD (Petition 1 at 2). You assert that section 505(b)(2), or a petitioned ANDA under 505(j)(2)(C), would be the appropriate route of approval in cases where an auto-injector is not the "same" as that in an RLD, and such applications would need to include clinical studies demonstrating the safety and effectiveness of the auto-injector.

We deny your request that we require clinical trials in every 505(b)(2) application for a combination product that includes an auto-injector constituent part that is different from the auto-injector of the listed drug referenced. The need for clinical trials is determined on a case-by-case basis and depends on a number of factors. Clinical trials may not always be required (see the guidance for industry on *Applications Covered by Section 505(b)(2)*[7]). We agree, however, that some auto-injector changes (e.g., a change to the needle hub assembly, different operating principles, different ergonomics) may require further clinical data because potential clinical consequences might be unknown. Further, in instances where proper usage by a targeted patient population is in question, additional studies such as human factor analysis, actual use studies, and labeling comprehension studies may be warranted. These are not universally required, however.

Your requested action also refers to suitability petitions. We consider individual suitability petitions as they are received. We note, however, that the dosage form for sumatriptan auto-injectors is "injectable" and does not change with the particular injector used. Changes permitted in suitability petitions are limited to changes in active ingredient, route of administration, dosage form, or strength.[8] Thus, an ANDA suitability petition does not appear to be an appropriate vehicle for a combination product seeking to use an auto-injector different from the listed drug it references, because a change in the auto-injector constituent of a combination product is not a petitionable change. Furthermore, ANDA suitability petitions are granted only when clinical studies are not necessary to show safety and effectiveness of the proposed drug. Thus, if clinical studies are necessary, the suitability petition route to approval would not be appropriate.[9]

D. Comparative Performance Testing

You request that the Agency not determine that a product containing an auto-injector is therapeutically equivalent to another product containing an auto-injector without a demonstration that it delivers identical amounts of the active ingredients in an identical dispensing time based on comparative performance testing (Petition 1 at 9). As grounds

[7] Available on the Internet at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079345.pdf.

[8] See 21 U.S.C. 355(j)(2)(C); 21 CFR 314.93(a) and (b).

[9] See 21 CFR 314.93(e)(1).

for your request, you state that auto-injectors are designed for two distinct routes of administration, intramuscular or subcutaneous. You note that automated mechanisms, rather than trained medical personnel, are central to drug delivery for these products. Given this reliance on automated mechanisms, you specify performance testing comparing extended needle length, depth of penetration, activation force, and dispensing time to ensure that the proposed product's auto-injector uses the same route of administration as the RLD.

We agree that comparative performance testing, including, but not limited to, extended needle length, needle integrity, activation force, dispensing time, and dispensing volume, is required for ANDA approval. These are critical elements in establishing dose accuracy. We do not agree, however, that this is the only type of performance specification that an ANDA applicant should submit. For example, FDA also recommends that ANDA sponsors provide specifications such as activation force, breakloose force, extrusion force, needle gauge, and needle protrusion.

E. Dosage Form and Orange Book Issues

In both petitions, you inquire about Orange Book listing issues for auto-injectors. In Petition 1, you request that FDA establish, in the Orange Book, new auto-injector "dosage forms" that distinguish among auto-injectors with significant differences in administration and physical appearance, and also distinguish auto-injectors from other injectable dosage forms. You request that, at a minimum, dosage forms for combination products containing auto-injectors distinguish pressure-activated auto-injectors from those that require use of a firing button, and distinguish among prefilled fully-assembled auto-injectors, multiple-dose auto-injectors, and auto-injectors equipped with cartridges requiring assembly (Petition 1 at 10-11). In Petition 2, you reiterate the same request and add specific references to sumatripan, requesting that in conjunction with the approval of any injectable sumatriptan ANDA, the Agency clarify drug nomenclature to ensure consistent identification of dosage form, route of administration, and strength for all drug products containing sumatriptan (Petition 2 at 2).

In elaborating on your contention that FDA's current classification of auto-injectors is confusing, you cite, by way of example, the Orange Book's listing of the Imitrex vial product and auto-injector product together for many years, and then, in 2007, its listing of the vial and auto-injector products separately, even as both products "remain classified under the same dosage form and route of administration and are not further distinguished" (Petition 2 at 2).[10] Finally, you add that FDA's public information regarding Paragraph IV certifications and tentative approvals demonstrates a lack of clarity regarding auto-injector classification.

[10] To clarify, the manufacturer of Imitrex, GlaxoSmithKline, discontinued marketing the unit-of-use Imitrex prefilled syringe for commercial reasons in 2004, as noted in its annual report. We will assess whether an update to the Orange Book is needed as a result. In any event, we note that the Paragraph IV certification page does not include "pre-filled syringe" in the dosage form column; it is instead listed in the strength column.

FDA recognizes that there may be multiple approaches to registration, listing, coding, and other methods to characterize combination products composed of a drug constituent part and an auto-injector constituent part. We are actively considering whether the Orange Book, which was not designed to separately address combination product listings or to identify the specific type of drug delivery system, could benefit from enhanced listing capabilities. The Agency is considering a broad range of approaches to ensure consistency in identifying products.

We do not, however, agree that any action on a relevant application and changes in our databases must be concurrent. Delays of approval of otherwise approvable applications while we consider whether to make changes to the Orange Book or other databases would not be justified.

You also request that in the absence of a determination that auto-injectors with different release mechanisms qualify as different dosage forms, the Agency agree that differences among auto-injector release mechanisms would satisfy criteria under 21 CFR 314.127(a)(8)(ii)(A) for refusing to approve an ANDA because "there is a reasonable basis to conclude that one or more of the inactive ingredients of the proposed drug or its composition raises serious questions of safety or efficacy" (Petition 1 at 11). As noted above, the Agency agrees that differences among auto-injector release mechanisms may raise serious questions of safety or efficacy. As further noted, the Agency may refuse to approve an ANDA with an auto-injector on the ground that differences from the RLD auto-injector may lead to differences in safety or efficacy. A finding of this kind by the Agency, however, would be very case-specific and the basis for the determination would depend on the particular characteristics of the product.

F. Labeling

You contend that for combination products including an auto-injector constituent, the requirement that labeling be "the same" does not permit differences in operating instructions or graphic illustrations. You request that FDA require ANDA sponsors of drug products containing auto-injectors to use the same physical description of an auto-injector, the same operating instructions, and the same illustrations contained in the RLD labeling, and to ensure that such labeling applies equally to the proposed auto-injector. You add that the same standard should apply in assessing therapeutic equivalence (Petition 1 at 12).

As noted above, we agree that the auto-injector constituent in an ANDA for a combination product should be equivalent to that of the RLD product in terms of performance, operating principles, and critical design attributes. However, labeling need not be identical. Certain minor labeling changes may be acceptable to identify certain permissible differences between the ANDA and its RLD (e.g., to identify a change in materials to make the product lighter or to make it more robust or durable), as are minor differences (such as cosmetic appearance, color, shape) between the RLD and ANDA labeling when they do not interfere with operating conditions. For products that require physician training before unsupervised patient use, differences in operation that require

retraining prior to use are not expected to be acceptable in an ANDA. FDA will consider other proposed differences in labeling on a case-by-case basis.

G. Waivers of Bioequivalence Studies

You request that we grant waivers of in vivo bioequivalence studies, such as those applicable to parenteral solutions intended solely for administration by injection, for combination products containing auto-injectors only in the presence of "other data" (21 CFR 320.22(b)(1)) in the form of comparative performance testing. You further state that such testing should show that the auto-injector used in a proposed drug product will "(i) deliver the same amount of drug (ii) to the same area (iii) in the same amount of time (iv) with the same force (v) under similar conditions" (Petition 1 at 13).

As noted above, we agree that comparative performance testing is a requirement for demonstrating bioequivalence of drug/auto-injector combination products. We also agree that to obtain a waiver of in vivo testing for a demonstration of bioequivalence, proposed sumatriptan auto-injector products must have the same active and inactive ingredient in the same concentration as the RLD, and sponsors must provide performance test evidence that includes a demonstration that their auto-injector and that in the RLD have similar needle penetration depth, dispensing time, dispensed volume, and injection force. The testing requirements you recommend in your petition (Petition 1 at 13) already reflect current Agency practice.

H. Request for Guidance

You request that the Agency develop guidance on appropriate methods for demonstrating bioequivalence to a combination product containing an auto-injector (Petition 1 at 7). You note the announcement of pending guidance in Petition 2 (Petition 2 at 2).

On April 27, 2009, the Agency published *Draft Guidance to Industry and FDA Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products*. After receiving comment on this draft guidance, the Agency may consider whether focused guidance for ANDAs for particular products would be appropriate. In the interim, the Agency will continue to work with sponsors on issues pertaining to the demonstration of therapeutic equivalence for combination products containing auto-injectors. In any event, we disagree with your suggestion that *the absence of guidance* may reflect an internal conclusion by the Agency that the ANDA pathway is not suitable for any combination product containing an auto-injector.

III. CONCLUSION

For the reasons discussed above, your petitions are granted in part and denied in part.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

v. CIVIL ACTION NO. _____

KAREN L. BOWLING, Secretary
of the West Virginia Department
of Health and Human Resources,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S
MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT J

SPILMAN THOMAS & BATTLE, PLLC
ATTORNEYS AT LAW

Brian C. Helmick
304.340.3826
bhelmick@spilmanlaw.com

February 27, 2015

Karen Villanueva-Matkovich, Esq.
General Counsel
West Virginia Department of Health and Human Resources
One Davis Square, Suite 100E
Charleston, WV 25301

Re: *Freedom of Information Act Request*

Dear Ms. Villanueva-Matkovich:

Pursuant to the West Virginia Freedom of Information Act, W. Va. Code § 29B-1-1 *et seq.*, I am requesting that you provide me with copies of all public records, including without limitation all writings, documents, minutes, reports, correspondence or other information, including all letters, e-mails, memoranda and attachments, whether prepared by, for, on behalf of, or submitted to, the West Virginia Department of Health and Human Resources, the West Virginia Bureau of Medical Services, the West Virginia Pharmaceutical and Therapeutics Committee, or the West Virginia Drug Utilization Review Board relating to or in any way refers to the following between January 1, 2014 and the date of this request, within the statutory five-day period:

1. EpiPen® Auto-Injector;

2. EpiPen Jr® Auto-Injector;

3. Epinephrine auto-injectors;

4. Magellan Medicaid Administration, Inc.'s recommendation and the West Virginia Pharmaceutical and Therapeutics Committee's decision that EpiPen® and EpiPen Jr® be removed from preferred status on the West Virginia Medicaid Preferred Drug list;

5. Termination for preferred positioning of all rebate-eligible National Drug Codes of Epi-Pen and Epi-Pen Junior on the West Virginia Medicaid Preferred Drug list; and

6. Any educational materials, notices, bulletins or correspondence advising, informing or educating the general public or medical community respecting or relating to the West Virginia Pharmaceutical and Therapeutics Committee's decision that EpiPen® and EpiPen Jr® be removed from preferred status on the West Virginia Medicaid Preferred Drug list.

Please note that we recognize the exemption of certain materials and information under W. Va. Code §9-5-15, which exempts certain "Trade secrets, rebate amounts, percentage of rebate, manufacturer's pricing and supplemental rebates which are contained in the department's records and those of its agents with respect to supplemental rebate negotiations and which are prepared pursuant to a supplemental rebate agreement are confidential and exempt from all of article one, chapter twenty-nine-b of this code [West Virginia Freedom of Information Act] . . ." and "[t]hose portions of any meetings of the committee at which trade secrets, rebate amounts, percentage of rebate, manufacturer's pricing and supplemental rebates are disclosed for discussion or negotiation of a supplemental rebate agreement are exempt from all of article nine-a, chapter six of this code [Open Governmental Proceedings Act]." Consequently, if any of the requested public records contain any such exempted information, please feel free to redact those portions of such records so affected. Additionally, please identify in writing any public records for which you feel cannot be appropriately redacted and withhold from disclosure in its entirety.

I appreciate your attention to this request and ask that you please feel free to contact me with any questions. Otherwise, I look forward to your response identifying where I may collect or make copies of responsive documents.

Very truly yours,

Brian Helmick

Brian C. Helmick

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

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KAREN L. BOWLING, Secretary
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Defendant.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S
MOTION FOR A STATUS QUO PRELIMINARY INJUNCTION

EXHIBIT K

Cunningham, Vicki M

From: Bandali, Nina <NBandali@magellanhealth.com>
Sent: Wednesday, November 05, 2014 7:19 PM
To: Cunningham, Vicki M
Subject: RE: October P&T Committee Question

Hi Vicki,

Sure, we can further discuss on Friday. Regarding whether to consider their offer, it depends on what Emdeon's solicitation states or what they tell the MFR. Do they provide deadlines and tell them that only their BAFO should be submitted? If addition, if P&T votes to maintain Epipen as preferred then, of course, we should take their enhanced offer.

Let's talk on Friday.

Thanks,
Nina

From: Cunningham, Vicki M [mailto:Vicki.M.Cunningham@wv.gov]
Sent: Wednesday, November 05, 2014 6:01 PM
To: Bandali, Nina
Subject: FW: October P&T Committee Question

Hi Nina!
I would like to talk about the Epipen situation on Friday. I am confused about the Committee's intention. I heard they want us to have time to do education, but we can't educate if they haven't made a decision. The offer from Mylan was very late, and in my opinion, shouldn't be considered. Do you agree?
Vicki

Vicki.M.Cunningham, R.Ph.
Director of Pharmacy Services
Bureau for Medical Services
Phone 304-356-4857
FAX 304-558-1542
e-mail Vicki.M.Cunningham@wv.gov

From: Thomas Letizia [mailto:Thomas.Letizia@mylan.com]
Sent: Wednesday, November 05, 2014 4:13 PM
To: Cunningham, Vicki M
Subject: October P&T Committee Question

Hi Vickie,

My name is Tom Letizia and am a Regional Account Manager for Mylan Pharmaceuticals. I recently attended the WV State P&T Committee meeting and just had a few questions in regards to EpiPen® Auto-Injector as the committee decided to table discussions until the 1/28/15 meeting.

First, I wanted to confirm that you received the most recent supplemental rebate offer that we submitted through Goold at the end of September? Also, since the rebate offer was submitted after the Draft PDL was posted on the WV website we were concerned that maybe the most recent pricing was not considered when the pre meeting recommendations were stated at the meeting.

When the committee decided to push the discussion to the next meeting they mention needing more information to review. If there is any additional information I can provide you in regards to EpiPen® Auto-Injector please let me know. We currently have an EpiPen® Auto-Injector Dossier available that I can submit if you feel this would help.

I didn't want to bother you with a phone call if you have 10-15min tomorrow or Friday it might be easier to have this conversation over the phone. Thanks so much and sorry all the question.

Regards,

Tom Letizia
Regional Account Manager
Managed Markets
Mylan Specialty L.P.
C: 862-259-1661
E: thomas.letizia@mylan.com

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

MYLAN SPECIALTY L.P.,

Plaintiff,

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KAREN L. BOWLING, Secretary
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EXHIBIT L

SSDC Offer Update – Epinephrine Pens (10/9/14)

You may recall that, at the Annual SSDC Meeting in June, I noted that there were some issues with units, pricing, offers and availability of some epinephrine pen products and that we were working with the manufacturers to clarify and rectify those issues. Once we received the required information from all of the manufacturers, I requested that they submit BAFOs. The attached offer for EpiPen represents the final of those BAFO offers (sanofi-aventis' BAFO for Auvi-Q was included in the 7/25/14 SSDC Supplemental Rebate Offer Update).

The EpiPen BAFO represents a significant improvement over the original offer. Initially, Mylan made only a Tier 1 offer for 15% of WAC. Having the bulk of the utilization in most states made this offer compelling, even though EpiPen had the highest net cost of any of the epinephrine pen products. The BAFO submitted for EpiPen provides an enhanced offer for Tier 1 [redacted] and also provides, for the first time, a Tier 2 offer [redacted]

The sanofi-aventis offer that was sent out in July also represents a significant enhancement of their initial offer. While both offers are [redacted] the GNP has been reduced from [redacted]

We did not receive offers for Adrenaclick or for the authorized generic of that product. With no SR, Adrenaclick is costly with an average net cost of [redacted] The average net cost of the authorized generic is [redacted] The manufacturer informed me, however, that they have had some supply issues, especially with the 0.15 mg pen. They expect those issues to be resolved sometime this month, but I still question their ability to provide product consistently on an ongoing basis.

The Auvi-Q offer makes it the least costly of these products; the net cost for 2 pens is [redacted] net of the [redacted] SR. While the new EpiPen offer is an improvement over previous offers, its net cost is still relatively high. At Tier 1, the net cost for 2 pens is [redacted] net of [redacted]; at Tier 2, the net cost is [redacted] net of [redacted]

While EpiPen is more costly than Auvi-Q and the authorized generic, it has nearly all of the market share in most states. The ability to move that market share has been, and continues to be, a critical consideration when evaluating this class. With the availability of a Tier 2 offer for EpiPen and the significant cost difference between it and Auvi-Q, consideration could be given to adding Auvi-Q as a second preferred product in this class. While there is some variation among the SSDC states in reimbursement and relative market shares, states that currently have EpiPen as the sole preferred product could add Auvi-Q and break even if Auvi-Q picks up [redacted] of the EpiPen market share. If Auvi-Q fails to pick up that market share, then the state is better off maintaining EpiPen as the sole preferred agent.

Of course, another option would be to make Auvi-Q the sole preferred epinephrine pen. To account for the loss of the EpiPen Tier 1 SR, states would have to move [redacted] EpiPen market share to Auvi-Q to break even.

RECOMMENDATION SUMMARY

I think it is doubtful that, if co-preferred with EpiPen, Auvi-Q would garner [redacted] of the market share, so co-preferring it with EpiPen would more likely result in an overall increase in net expenditures. With a very aggressive PA program, it might be possible for a state to move [redacted] the EpiPen utilization if Auvi-Q were the sole preferred product. Even with that, net expenditures would be about the same as if the state took the Tier 1 EpiPen offer.

While the dynamics are different in each state, overall I think that most states will be better off accepting the EpiPen Tier 1 offer.