IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

K-V Pharmaceutical Company, Ther-RX Corporation,	)	
Plaintiffs,	)	**CASE NO.: 3:12-cv-02088-MBS**
vs.	)	
Anthony Keck, in his official capacity as Director of Health and Human Services for the State of South Carolina,	)	
Defendant.	)	

DEFENDANT'S REPLY MEMORANDUM
IN SUPPORT OF HIS MOTION TO DISMISS

Defendant Anthony Keck ("Director Keck"), in his official capacity as the Director of the South Carolina Department of Health and Human Services ("SCDHHS"), respectfully submits his reply in further support of Defendant's Motion to Dismiss, and states again that dismissal is proper under Federal Rule of Civil Procedure, Rule 12(b)(6) for failure to state a cause of action upon which relief can be granted. In their complaint, Plaintiffs KV Pharmaceutical and Ther-RX (collectively "KV") failed to properly plead standing under the Supremacy Clause, and instead moved for temporary injunctive relief based upon the existence of a private right of action under the Federal Medicaid Act, though KV now concedes no such action exists.

Furthermore, KV's efforts to explain that they intended to bring their claim under the Supremacy Clause are unavailing. Though the Court may recognize that KV has standing under the Supremacy Clause, KV will be unable, as a matter of law, to

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA COLUMBIA DIVISION

K-V Pharmaceutical Company,) Ther-RX Corporation,)) Plaintiffs,) CASE NO.: 3:12-cv-02088-MBS

) vs.)) Anthony Keck, in his official capacity as) Director of Health and Human Services) for the State of South Carolina,)) Defendant.))

DEFENDANT'S REPLY MEMORANDUM IN SUPPORT OF HIS MOTION TO DISMISS

Defendant Anthony Keck ("Director Keck"), in his official capacity as the Director of the South Carolina Department of Health and Human Services ("SCDHHS"), respectfully submits his reply in further support of Defendant's Motion to Dismiss, and states again that dismissal is proper under Federal Rule of Civil Procedure, Rule 12(b)(6) for failure to state a cause of action upon which relief can be granted. In their complaint, Plaintiffs KV Pharmaceutical and Ther-RX (collectively "KV") failed to properly plead standing under the Supremacy Clause, and instead moved for temporary injunctive relief based upon the existence of a private right of action under the Federal Medicaid Act, though KV now concedes no such action exists.

Furthermore, KV's efforts to explain that they intended to bring their claim under the Supremacy Clause are unavailing. Though the Court may recognize that KV has standing under the Supremacy Clause, KV will be unable, as a matter of law, to

successfully argue that SCDHHS's physician administered prior authorization policy conflicts with federal law, and is therefore preempted.

KV also continues to make unsubstantiated allegations about the numerous denials SCDHHS has issued to requests for Makena. KV fails to acknowledge, however, that South Carolina uses two separate systems for drug reimbursement. The pharmaceutical reimbursement system, which uses the Magellan Drug Lookup, reimburses for home administered drugs, whereas the physician administered system reimburses for those drugs which must be administered by a physician. Makena is considered a physician administered drug, and therefore any request for Makena that went through the pharmaceutical reimbursement channels would be denied. Requests for Makena, and other physician administered drugs subject to prior authorization, must be made directly to SCDHHS. To date, no requests for Makena have been submitted to the physician administered program.

In arguing that dismissal is improper, KV also relies heavily on the recently issued opinion in KV's case against the Georgia state Medicaid agency. At the time the opinion was issued, Georgia had not yet filed its Motion to Dismiss. In addition, South Carolina's physician administered prior authorization policy is distinct, on its face, from the Georgia prior authorization policy for Makena. Finally, the Georgia opinion went solely to the issuance of a temporary injunction, and was not an opinion on the underlying merits of KV's claims. Therefore, this opinion has no impact on South Carolina's Motion to Dismiss.

successfully argue that SCDHHS's physician administered prior authorization policy conflicts with federal law, and is therefore preempted.

KV also continues to make unsubstantiated allegations about the numerous denials SCDHHS has issued to requests for Makena. KV fails to acknowledge, however, that South Carolina uses two separate systems for drug reimbursement. The pharmaceutical reimbursement system, which uses the Magellan Drug Lookup, reimburses for home administered drugs, whereas the physician administered system reimburses for those drugs which must be administered by a physician. Makena is considered a physician administered drug, and therefore any request for Makena that went through the pharmaceutical reimbursement channels would be denied. Requests for

Makena, and other physician administered drugs subject to prior authorization, must be made directly to SCDHHS. To date, no requests for Makena have been submitted to the physician administered program.

In arguing that dismissal is improper, KV also relies heavily on the recently issued opinion in KV's case against the Georgia state Medicaid agency. At the time the opinion was issued, Georgia had not yet filed its Motion to Dismiss. In addition, South Carolina's physician administered prior authorization policy is distinct, on its face, from the Georgia prior authorization policy for Makena. Finally, the Georgia opinion went solely to the issuance of a temporary injunction, and was not an opinion on the underlying merits of KV's claims. Therefore, this opinion has no impact on South Carolina's Motion to Dismiss.

FACTUAL BACKGROUND

KV continues to allege that a history of 17 Alpha-Hydroxyprogesterone Caproate ("17P") is irrelevant to any discussion of Makena. KV hopes to distract the Court from the nearly six (6) decade history of 17P, and also from SCDHHS's continuing efforts to work with physicians statewide to prevent preterm birth. Instead, KV would have the Court believe that KV alone developed and produced this drug, and that the compounds came after, and incident to, Makena's appearance on the market.

In reality, 17P has been available since 1956 as the FDA approved drug Delalutin. In 2000, Bristol-Meyers, the sponsor of Delalutin, pulled the NDA from the United States' market, for reasons unrelated to safety. Following the market withdrawal of the Delalutin NDA, prescribing physicians ordered compounded 17P.

In 2003, the first complete study on the impact of 17P in preventing preterm birth was released. Named after its lead investigator, the Meis study was met with great enthusiasm by the OB-GYN community, and physicians began to prescribe 17P for women at-risk for preterm birth – significantly, women who had already experienced spontaneous preterm labor (distinct from induced preterm labor).

In 2005, South Carolina Department of Health and Environmental Control's OB-Task force worked in conjunction with SCDHHS to make 17P available to South Carolina women. Because of its short shelf life, compounding pharmacies make 17P per individual prescription received.

Meanwhile, in 2008, the FDA received a tip-off about potential manufacturing discrepancies at KV. After an investigation that ranged from October 2008 through February 2009, the FDA seized approximately $24 million dollars worth of

FACTUAL BACKGROUND

KV continues to allege that a history of 17 Alpha-Hydroxyprogesterone Caproate ("17P") is irrelevant to any discussion of Makena. KV hopes to distract the Court from the nearly six (6) decade history of 17P, and also from SCDHHS's continuing efforts to work with physicians statewide to prevent preterm birth. Instead, KV would have the Court believe that KV alone developed and produced this drug, and that the compounds came after, and incident to, Makena's appearance on the market.

In reality, 17P has been available since 1956 as the FDA approved drug Delalutin. In 2000, Bristol-Meyers, the sponsor of Delalutin, pulled the NDA from the United States' market, for reasons unrelated to safety. Following the market withdrawal of the Delalutin NDA, prescribing physicians ordered compounded 17P.

In 2003, the first complete study on the impact of 17P in preventing preterm birth was released. Named after its lead investigator, the Meis study was met with great enthusiasm by the OB-GYN community, and physicians began to prescribe 17P for women at-risk for preterm birth – significantly, women who had already experienced spontaneous preterm labor (distinct from induced preterm labor).

In 2005, South Carolina Department of Health and Environmental Control's OB-Task force worked in conjunction with SCDHHS to make 17P available to South Carolina women. Because of its short shelf life, compounding pharmacies make 17P per

individual prescription received.

Meanwhile, in 2008, the FDA received a tip-off about potential manufacturing discrepancies at KV. After an investigation that ranged from October 2008 through February 2009, the FDA seized approximately $24 million dollars worth of

pharmaceutical products from KV, and sanctioned them for misbranding and mislabeling.[1]

In 2011, just days before another manufacturer gained FDA approval for the 17P NDA, KV purchased the drug for roughly $195 Million. KV was not a participant in the FDA approval process, had not conducted a single study with the drug, nor had KV adequately tested the drug's existing market. While KV cites to the support it received from the March of Dimes and other proponents to help end prematurity, this support was actively withdrawn when those proponents saw the price tag KV affixed to its product. KV assumed they had cornered the market on a product, but failed to assess the trust that physicians placed in the existing compounds, which had been the subjects of extensive study for nearly a decade.

Despite KV's failure to analyze the market for Makena, and gauging physician receptivity to a drug other than compound 17P, Makena was released as a covered drug in South Carolina in February of 2011. Following Makena's release to the market, SCDHHS announced that the state's physician administered prior authorization policy would apply to the drug. This policy, which is the same policy used for all physician administered drugs that require prior authorization, requires a physician to identify the drug's medical necessity and clinical indication prior to approval. Physicians regularly prescribe drugs subject to this policy, and are in no way deterred by it.

---

[1] When ruling on a 12(b)(6) motion, the court may examine the complaint, any documents attached to or incorporated in the complaint, items in the record of the case, and of which the court may take judicial notice. 138 A.L.R. Fed. 393. In considering a motion to dismiss based upon Rule 12(b)(6) the court may consider, "in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Katyle v. Penn Nat. Gaming, Inc.* 637 F.3d 462, 466 (4th 2011) citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322, 127 S.Ct. 2499,168 L.Ed.2d 179 (2007).

pharmaceutical products from KV, and sanctioned them for misbranding and mislabeling.1

In 2011, just days before another manufacturer gained FDA approval for the 17P NDA, KV purchased the drug for roughly $195 Million. KV was not a participant in the FDA approval process, had not conducted a single study with the drug, nor had KV adequately tested the drug's existing market. While KV cites to the support it received from the March of Dimes and other proponents to help end prematurity, this support was actively withdrawn when those proponents saw the price tag KV affixed to its product. KV assumed they had cornered the market on a product, but failed to assess the trust that physicians placed in the existing compounds, which had been the subjects of extensive study for nearly a decade.

Despite KV's failure to analyze the market for Makena, and gauging physician receptivity to a drug other than compound 17P, Makena was released as a covered drug in South Carolina in February of 2011. Following Makena's release to the market, SCDHHS announced that the state's physician administered prior authorization policy would apply to the drug. This policy, which is the same policy used for all physician administered drugs that require prior authorization, requires a physician to identify the drug's medical necessity and clinical indication prior to approval. Physicians regularly prescribe drugs subject to this policy, and are in no way deterred by it.

1 When ruling on a 12(b)(6) motion, the court may examine the complaint, any documents attached to or incorporated in the complaint, items in the record of the case, and of which the court may take judicial notice. 138 A.L.R. Fed. 393. In considering a motion to dismiss based upon Rule 12(b)(6) the court may consider, "in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." Katyle v. Penn Nat. Gaming, Inc. 637 F.3d 462, 466 (4th 2011) citing Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322, 127 S.Ct. 2499,168 L.Ed.2d 179 (2007).

DISCUSSION AND CITATION TO AUTHORITY

I. *KV HAS CONCEDED THAT NO PRIVATE RIGHT OF ACTION EXISTS TO SUPPORT ITS ALLEGATIONS AGAINST SCDHHS.*

In its complaint for injunctive relief, KV failed to properly plead jurisdiction pursuant to the Supremacy Clause, and instead attempted to argue jurisdiction pursuant to based upon an alleged private right of action. In its Memorandum in Opposition to Defendant's Motion to Dismiss, KV backtracks on its earlier argument, and instead states that jurisdiction under §1983 was never alleged. Rather, KV argues that the sole basis for its current action against Director Keek is the Supremacy Clause, and the alleged conflict between South Carolina's prior authorization policy and the Federal Medicaid Act. Therefore, based upon KV's own admissions, KV does not have standing based on a private right of action, and the only way KV can succeed on its underlying claims is to prove that a conflict exists between state and federal law.

II. *KV HAS FAILED TO ALLEGE SUFFICIENT FACTS TO SUPPORT ITS ARGUMENT THAT SCDHHS'S PHYSICIAN ADMINISTRED PRIOR AUTHORIZATION POLICY CONFLICTS WITH FEDERAL LAW, AND THEREFORE ITS CLAIMS MUST BE DIMISSED.*

Despite the fact that the South Carolina state plan is written "in compliance with Section [1396r-8] of the Social Security Act," KV alleges entitlement to injunctive relief because the South Carolina physician administered prior authorization policy supposedly conflicts with Federal Law.

a. Under Implied Conflict Preemption, South Carolina's Prior Authorization Policy Plainly Abides by the Requirements of the Federal Medicaid Act.

In *PhRMA v. Concannon*, 249 F.3d 66 (1st Cir.Ct.App., 2001), the First Circuit Court of Appeals reversed a temporary injunction issued by the District Court against a

DISCUSSION AND CITATION TO AUTHORITY

I. KV HAS CONCEDED THAT NO PRIVATE RIGHT OF ACTION EXISTS TO SUPPORT ITS ALLEGATIONS AGAINST SCDHHS.

In its complaint for injunctive relief, KV failed to properly plead jurisdiction pursuant to the Supremacy Clause, and instead attempted to argue jurisdiction pursuant to based upon an alleged private right of action. In its Memorandum in Opposition to Defendant's Motion to Dismiss, KV backtracks on its earlier argument, and instead states that jurisdiction under §1983 was never alleged. Rather, KV argues that the sole basis for its current action against Director Keck is the Supremacy Clause, and the alleged conflict between South Carolina's prior authorization policy and the Federal Medicaid Act. Therefore, based upon KV's own admissions, KV does not have standing based on a private right of action, and the only way KV can succeed on its underlying claims is to prove that a conflict exists between state and federal law.

II. KV HAS FAILED TO ALLEGE SUFFICIENT FACTS TO SUPPORT ITS ARGUMENT THAT SCDHHS'S PHYSICIAN ADMINISTRED PRIOR AUTHORIZATION POLICY CONFLICTS WITH FEDERAL LAW, AND THEREFORE ITS CLAIMS MUST BE DIMISSED.

Despite the fact that the South Carolina state plan is written "in compliance with Section [1396r-8] of the Social Security Act," KV alleges entitlement to injunctive relief because the South Carolina physician administered prior authorization policy supposedly conflicts with Federal Law.

a. Under Implied Conflict Preemption, South Carolina's Prior Authorization Policy Plainly Abides by the Requirements of the Federal Medicaid Act.

In PhRMA v. Concannon, 249 F.3d 66 (1st Cir.Ct.App., 2001), the First Circuit Court of Appeals reversed a temporary injunction issued by the District Court against a

State Medicaid Plan. There were two (2) issues before the Court. First, whether the PhRMA had standing to challenge a state Medicaid plan's prior authorization policy, second, whether the policy conflicted with federal law.

The Court of Appeals determined first that PhRMA did have standing. *Id.* at 73. The Court found that, rather than asserting an action to enforce rights under the Medicaid statue, the PhRMA alleged a "preemption-based challenge under the Supremacy Clause." *Id.* The Court concluded that "regardless of whether the Medicaid statute's relevant provisions were designated to benefit PhRMA, PhRMA could invoke the statute's preemptive force." *Id.*

The Court then considered whether the challenged state prior authorization policy actually conflicted with the federal Medicaid Act. The Court found no basis for preemption.

The parties agreed that only implied conflict preemption was at issue, and therefore the Court considered only whether "compliance with both state and federal regulations is possible," or if "state law interposes an obstacle to the achievement of Congress's discernable objectives." *Id.* at 75. The Court noted that "federal preemption of a state law is strong medicine…not casually to be dispensed," especially when the federal statute creates a program like Medicaid that utilizes cooperative federalism. *See Wash., Dep't. of Soc. & Health Servs. v. Bowen*, 815 F.2d 549, 557 (9th Cir. 1987) ("Where coordinated state and federal efforts exist within a complimentary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one.")

State Medicaid Plan. There were two (2) issues before the Court. First, whether the PhRMA had standing to challenge a state Medicaid plan's prior authorization policy; second, whether the policy conflicted with federal law.

The Court of Appeals determined first that PhRMA did have standing. Id. at 73. The Court found that, rather than asserting an action to enforce rights under the Medicaid statue, the PhRMA alleged a "preemption-based challenge under the Supremacy Clause." Id. The Court concluded that "regardless of whether the Medicaid statute's relevant provisions were designated to benefit PhRMA, PhRMA could invoke the statute's preemptive force." Id.

The Court then considered whether the challenged state prior authorization policy actually conflicted with the federal Medicaid Act. The Court found no basis for preemption.

The parties agreed that only implied conflict preemption was at issue, and therefore the Court considered only whether "compliance with both state and federal regulations is possible," or if "state law interposes an obstacle to the achievement of Congress's discernable objectives." Id. at 75. The Court noted that "federal preemption of a state law is strong medicine...not casually to be dispensed," especially when the federal statute creates a program like Medicaid that utilizes cooperative federalism. See Wash., *Dep't. of Soc. & Health Servs. v. Bowen, 815 F.2d 549, 557 (9th Cir. 1987) ("Where* coordinated state and federal efforts exist within a complimentary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one.")

Ultimately, the Court found no conflict between the State's prior authorization policy and the structure and purpose of Medicaid. *Id.* at 75. "Neither the letter nor the intent of the Medicaid statute prevents states from imposing prior authorization requirements; indeed they are expressly permitted." *Id.* The Court also found that the plain language of the state act incorporated the two limitations on prior authorization policies specified in the Medicaid act, and contained the proviso that "[t]he department shall impose prior authorization requirements in the Medicaid program under this Title, as permitted by law..." The Court read the language to limit the Act's application to those situations where prior authorization was permitted by Medicaid, and further concluded that the State department was charged with administering the State Medicaid program, and was entitled to substantial deference in its interpretation of the Federal Act. *Id.*

In *PhRMA v. Walsh*, 538 U.S. 644, 123 S.Ct. 1855 (2003), the United States Supreme Court affirmed the 1st Circuit Court of Appeals' decision in *Concannon*, and concluded that the District Court had abused its discretion in granting a temporary injunction.

The Court noted that "[t]he presumption against federal preemption of a state statute designed to foster public health has special force when it appears, and the Secretary [of the United States Department of Health and Human Services] has not decided to the contrary, that the two governments, [state and federal], are pursing 'common purposes'" *Id.* at 667. The Court also pointed out that the state prior authorization programs were "made part of the Medicaid plans and approved by the Secretary..." *Id.*; 42 U.S.C. Section 1396a(b).

Ultimately, the Court found no conflict between the State's prior authorization policy and the structure and purpose of Medicaid. Id. at 75. "Neither the letter nor the intent of the Medicaid statute prevents states from imposing prior authorization requirements; indeed they are expressly permitted." Id. The Court also found that the plain language of the state act incorporated the two limitations on prior authorization policies specified in the Medicaid act, and contained the proviso that "[t]he department shall impose prior authorization requirements in the Medicaid program under this Title, as permitted by law..." The Court read the language to limit the Act's application to those situations where prior authorization was permitted by Medicaid, and further concluded that the State department was charged with administering the State Medicaid program, and was entitled to substantial deference in its interpretation of the Federal Act.

Id.

In PhRMA v. Walsh, 538 U.S. 644, 123 S.Ct. 1855 (2003), the United States Supreme Court affirmed the 1st Circuit Court of Appeals' decision in Concannon, and concluded that the District Court had abused its discretion in granting a temporary injunction.

The Court noted that "[t]he presumption against federal preemption of a state statute designed to foster public health has special force when it appears, and the Secretary [of the United States Department of Health and Human Services] has not decided to the contrary, that the two governments, [state and federal], are pursing 'common purposes'" Id. at 667. The Court also pointed out that the state prior authorization programs were "made part of the Medicaid plans and approved by the Secretary..." Id.; 42 U.S.C. Section 1396a(b).

The question before the Court in *Walsh* was whether the District Court had abused its discretion in issuing a temporary injunction against the State Medicaid Plan. *Walsh* at 661. Stated another way, the question for the Court to determine was "whether there is a probability that [the State] program was preempted by the mere existence of the federal statute." *Id.* The Court therefore started from the presumption that the state statute was valid, and asked whether PhRMA had shouldered the burden of overcoming that presumption. *Id.* at 661-662. The Court determined that PhRMA had not, and agreed with the Court of Appeals that PhRMA failed to demonstrate a conflict between the state prior authorization plan and the Federal law, that in the absence of a conflict the PhRMA alleged an insufficient basis for preemption of a state statute, and that the state program in question furthered the aims of the Federal Medicaid Act. *Id.* at 659.

Interestingly, *Concannon* and the *Walsh* opinion, almost exactly mirror the issue before this Court, namely whether a state's prior authorization policy is preempted by Federal law. South Carolina uses the same prior authorization policy for every physician administered drug that is covered, subject to prior authorization. Therefore, the policy in place over Makena in South Carolina is not unique to Makena, nor is it a policy designed to discourage prescribing physicians. In addition, to say that the policy conflicts with Federal law to the extent that it covers Makena, would implicate the policy as it relates to every other drug on the list. Furthermore, the South Carolina Plan includes a provison that the Plan is in compliance with the Federal Medicaid Act. SCDHHS, as the authority charged with administering state Medicaid benefits, is entitled to deference in its interpretation of the Federal law, and in its ability to craft a prior authorization policy.

The question before the Court in Walsh was whether the District Court had abused its discretion in issuing a temporary injunction against the State Medicaid Plan. Walsh at 661. Stated another way, the question for the Court to determine was "whether there is a probability that [the State] program was preempted by the mere existence of the federal statute." Id. The Court therefore started from the presumption that the state statute was valid, and asked whether PhRMA had shouldered the burden of overcoming that presumption. Id. at 661-662. The Court determined that PhRMA had not, and agreed with the Court of Appeals that PhRMA failed to demonstrate a conflict between the state prior authorization plan and the Federal law, that in the absence of a conflict the PhRMA alleged an insufficient basis for preemption of a state statute, and that the state program in question furthered the aims of the Federal Medicaid Act. Id. at 659.

Interestingly, Concannon and the Walsh opinion, almost exactly mirror the issue before this Court, namely whether a state's prior authorization policy is preempted by Federal law. South Carolina uses the same prior authorization policy for every physician administered drug that is covered, subject to prior authorization. Therefore, the policy in place over Makena in South Carolina is not unique to Makena, nor is it a policy designed to discourage prescribing physicians. In addition, to say that the policy conflicts with Federal law to the extent that it covers Makena, would implicate the policy as it relates to every other drug on the list. Furthermore, the South Carolina Plan includes a provison that the Plan is in compliance with the Federal Medicaid Act. SCDHHS, as the authority charged with administering state Medicaid benefits, is entitled to deference in its interpretation of the Federal law, and in its ability to craft a prior authorization policy.

Based on the plain language of South Carolina's prior authorization policy, as well as Congressional intent with regard to allowing State's to create prior authorization policies for covered drugs, no conflict with Federal law exists, and, likewise, no basis for preemption exists here. Therefore KV's claims fail as a matter of law.

b. In Practical Effect, South Carolina's Prior Authorization Policy Does Not Preclude Coverage of Physician Administered Drugs.

KV alleges that SCDHHS has denied every request for Makena received thus far. This allegation is not based on any substantiated facts, and is not entitled to an inference of truth. Both KV and SCDHHS have submitted competing affidavits regarding prescriptions of Makena submitted to the state. The discrepancies in these affidavits arise from KV's failure to take into account the two systems for submitting prior authorization requests to the state.

In South Carolina, a physician who wishes to prescribe a drug subject to prior authorization must either submit a request through Magellan, or directly to the SCDHHS, depending on whether the drug is considered a physician administered drug.

Upon information and belief, the affidavits that KV has submitted about prior authorization requests for Makena are all based upon requests submitted through Magellan. The only drugs covered by Magellan are pharmaceuticals that are administered at home. Makena is not one of these drugs. A prescription submitted to Magellan for Makena would always be denied, because in the case of physician administered drugs, the request must go directly to SCDHHS. In the event that a request improperly comes to Magellan rather than SCDHHS, Magellan sends out the following response:

> Reminder on Billing of Injectables Given in Physician Office: Injectables which are not self-administered by the recipient in their home, are not to be billed as a pharmacy

Based on the plain language of South Carolina's prior authorization policy, as well as Congressional intent with regard to allowing State's to create prior authorization policies for covered drugs, no conflict with Federal law exists, and, likewise, no basis for preemption exists here. Therefore KV's claims fail as a matter of law.

b. In Practical Effect, South Carolina's Prior Authorization Policy Does Not Preclude Coverage of Physician Administered Drugs.

KV alleges that SCDHHS has denied every request for Makena received thus far. This allegation is not based on any substantiated facts, and is not entitled to an inference of truth. Both KV and SCDHHS have submitted competing affidavits regarding prescriptions of Makena submitted to the state. The discrepancies in these affidavits arise from KV's failure to take into account the two systems for submitting prior authorization requests to the state.

In South Carolina, a physician who wishes to prescribe a drug subject to prior authorization must either submit a request through Magellan, or directly to the SCDHHS, depending on whether the drug is considered a physician administered drug. Upon information and belief, the affidavits that KV has submitted about prior authorization requests for Makena are all based upon requests submitted through Magellan. The only drugs covered by Magellan are pharmaceuticals that are administered at home. Makena is not one of these drugs. A prescription submitted to Magellan for Makena would always be denied, because in the case of physician administered drugs, the request must go directly to SCDHHS. In the event that a request improperly comes to Magellan rather than SCDHHS, Magellan sends out the following response:

Reminder on Billing of Injectables Given in Physician Office: Injectables which are not self-administered by the recipient in their home, are not to be billed as a pharmacy

> claim through the point of sale system (recipient going to local pharmacy to have the script filled and brought back to the office for administration). Non-home administered injectables should be billed as a physician service…

Thus, SCDHHS has never denied a request for Makena, because SCDHHS has never received one. This precludes KV from arguing that the effect of South Carolina's prior authorization policy is to exclude coverage of Makena. Furthermore, physicians prescribe drugs subject to the same prior authorization policy on a regular basis with no problem. Therefore, KV has failed to allege a conflict with state law, or to allege that the prior authorization policy that covers Makena operates to exclude coverage, since the same prior authorization policy does not exclude coverage of other drugs.

III. *KV'S RELIANCE ON THE OPINION ISSUED IN GEORGIA IS UNAVAILING BECAUSE THE SOUTH CAROLINA PRIOR AUTHORIZATION POLICY IS DISTINGUISHABLE FROM GEORGIA'S, AND THE GEORGIA OPINION DID NOT ADDRESS THE PREEMPTION ARGUMENT.*

In their Memorandum in Opposition to Defendant's Motion to Dismiss, KV relies heavily on the recently issued Georgia opinion in KV's case against the Georgia State Medicaid Agency. This opinion, however, has no precedential impact, and furthermore, is based on a much different set of facts than those before this court.

In Georgia, the state prior authorization policy expressly conditioned coverage of Makena on a patient's inability to use the compound. Therefore, absent a showing that the compound was inappropriate for a particular patient, a prescription for Makena would be denied. In South Carolina, however, the plain language of the prior authorization policy requires that the State cover a prescription for Makena where a requesting authority identifies that Makena is medically necessary and clinically indicated. This is the same prior authorization policy used for every other physician administered drug in

claim through the point of sale system (recipient going to local pharmacy to have the script filled and brought back to the office for administration). Non-home administered injectables should be billed as a physician service...

Thus, SCDHHS has never denied a request for Makena, because SCDHHS has never received one. This precludes KV from arguing that the effect of South Carolina's prior authorization policy is to exclude coverage of Makena. Furthermore, physicians prescribe drugs subject to the same prior authorization policy on a regular basis with no problem. Therefore, KV has failed to allege a conflict with state law, or to allege that the prior authorization policy that covers Makena operates to exclude coverage, since the same prior authorization policy does not exclude coverage of other drugs.

III. KV'S RELIANCE ON THE OPINION ISSUED IN GEORGIA IS UNAVAILING BECAUSE THE SOUTH CAROLINA PRIOR AUTHORIZATION POLICY IS DISTINGUISHABLE FROM GEORGIA'S, AND THE GEORGIA OPINION DID NOT ADDRESS THE PREEMPTION ARGUMENT.

In their Memorandum in Opposition to Defendant's Motion to Dismiss, KV relies heavily on the recently issued Georgia opinion in KV's case against the Georgia State Medicaid Agency. This opinion, however, has no precedential impact, and furthermore, is based on a much different set of facts than those before this court.

In Georgia, the state prior authorization policy expressly conditioned coverage of Makena on a patient's inability to use the compound. Therefore, absent a showing that the compound was inappropriate for a particular patient, a prescription for Makena would be denied. In South Carolina, however, the plain language of the prior authorization policy requires that the State cover a prescription for Makena where a requesting authority identifies that Makena is medically necessary and clinically indicated. This is the same prior authorization policy used for every other physician administered drug in