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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

UNITED STATES OF AMERICA *Ex rel.* Law Project for Psychiatric Rights, an Alaskan non-profit corporation, Plaintiff, vs. OSAMU H. MATSUTANI, MD, *et al.*, Defendants.	Case No. 3:09-CV-00080-TMB
UNITED STATES OF AMERICA, ex rel Daniel I. Griffin, Plaintiff, v.s RONALD A. MARTINO, MD., FAMILY CENTERED SERVICES OF ALASKA, INC., an Alaska corporation, and SAFEWAY, INC., a Delaware corporation, Defendants.	Case No. 3:09-CV-00246-TMB (CONSOLIDATED) **SUPPLEMENTAL BRIEF RE: DEFERENCE**

In the *Matsutani* Defendants' Reply in Support of Motion to Dismiss Under Rule 12(b)(6), Dkt. No. 120, at n. 40, and Safeway's Reply In Support of Motion to Dismiss

Relator Griffin's Complaint, Dkt. No. 154 at pages 7-8, the defendants argue the Center for Medicare and Medicaid Services (CMS), which is the federal agency charged with administering Medicaid, has interpreted the Medicaid statute to the effect that Congress did not restrict coverage of outpatient drugs to those that are for a "medically accepted indication." The merits of this issue have been extensively briefed previously,[1] and this supplemental brief will not repeat that briefing here, focusing instead on addressing the deference issue raised by the defendants in reply.

However, *relators* will present the issue in compact form. 42 USC 1396R-8(k)(3) provides, "The term 'covered outpatient drug' does not include any . . . drug . . . used for a medical indication which is not a medically accepted indication." 42 USC 1396R-8(k)(6) provides:

> The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

As succinctly stated by the court in *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass. 2008):

> Medicaid can only pay for drugs that are used for a "medically accepted indication," meaning one that is either approved by the FDA or "supported by citations" in one of three drug compendia, including DRUGDEX. See 42 U.S.C. § 1396r8 (k)(3), (6); 42 U.S.C. § 1396r-8 (g)(1)(B)(I).
>
> The defendants principally rely on 42 USC §1396r-8(d)(1)(B)(i), which provides:
>
> > (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--
> >
> > (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

The defendants' argument is this language implies Medicaid must cover more than "medically accepted indications."

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[1] *See*, Dkt. Nos. 102; 108; 120; 113, pp 4-6; & 151 pp 7-12.

Fundamentally, the defendants assert Congress did not limit coverage of outpatient drugs to "covered outpatient drugs," as defined in the statute to only include prescriptions for a "medically accepted indication." One of the arguments made by the defendants in support of this untenable position, raised only in reply at Dkt. 120, n.4, and Dkt. No. 154, pp 7-8, is CMS has taken the position that 42 USC §1396r-8(d)(1)(B)(i) allows Medicaid to pay for outpatient drugs that are not for a medically accepted indication, and this Court should give deference to that position notwithstanding that the Department of Justice has consistently taken the opposite position. The defendants' position is erroneous.

I. DEFERENCE STANDARDS

In support of their contention, at Dkt. No. 120, n. 40, the defendants assert CMS' interpretation that Congress did not restrict coverage for outpatient drugs to "covered outpatient drugs," should be given deference, citing *Citizens for Responsibility and Ethics in Washington v. U.S. Dept. of Justice*, [2] and *American Civil Liberties Union of N. Cal. v. Dept. of Justice*,[3] for the proposition that when DOJ is a party to litigation, its interpretation of a statute at issue is given no deference, and *Chevron U.S.A. Inc. v. NRDC*[4] and *Alaska D.H.H.S. v. C.M.S.*,[5] for the proposition this Court should give what is known as "*Chevron* deference" to CMS' interpretation.

The defendants claim *Chevron* deference is due, but ignore the more recent United States Supreme court decision in *U.S. v. Mead*[6], which was very recently addressed by the Ninth Circuit in *Northern California River Watch v. Wilcox*:[7]

> We begin our analysis with the "familiar two-step procedure" laid out in *Chevron*. At step one, we evaluate whether Congressional intent regarding the meaning of the text in question is clear from the statute's plain language. If it is, we must give effect to that meaning. If the statute is

[2] 658 F. Supp. 2d 217 (D.D.C. 2009)
[3] No. C 04-4447 PJH, 2005 WL 588354, at *8 (N.D. Cal. March 11, 2005)
[4] 467 U.S. 837, 842-45 (1984)
[5] 424 F.3d 931, 939-40 (9th Cir. 2005).
[6] 533 U.S. 218, 121 S.Ct. 2164 (2001).
[7] --- F.3d ----, 2010 WL 3329681, *4 (9th Cir. Aug 25, 2010), citations omitted.

> ambiguous, and an agency purports to interpret the ambiguity, prior to moving on to step two, we must determine whether the agency meets the requirements set forth in *Mead*: (1) that Congress clearly delegated authority to the agency to make rules carrying the force of law, and (2) that the agency interpretation was promulgated in the exercise of that authority. If both of these requirements from *Mead* are met, then we proceed to step two. Under step two, we must determine if the agency's interpretation of the statute is "a reasonable policy choice for the agency to make."

In *Marmolejo-Campos v. Holder*,[8] the Ninth Circuit had previously noted that under *Mead*:

> [B]efore we apply *Chevron*, we must conclude that Congress delegated authority to the agency to interpret the statute in question and that the agency decision under review was made with a "law-making pretense."

The Ninth Circuit then went on to note:[9]

> Thus, we have held that the Board's precedential orders, which bind third parties, qualify for *Chevron* deference because they are made with a "lawmaking pretense." We have not accorded *Chevron* deference to the Board's unpublished decisions, however, because they do not bind future parties.
>
> Nevertheless, *Skidmore* deference remains "intact and applicable" when an agency with rulemaking power interprets its governing statute without invoking such authority. Under *Skidmore*, the measure of deference afforded to the agency varies "depend[ing] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."

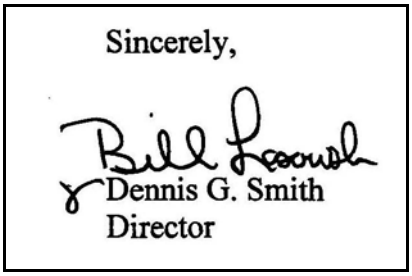
II. IT IS DUBIOUS THAT CMS HAS TAKEN THE POSITION CONGRESS DID NOT LIMIT COVERAGE OF OUTPATIENT DRUGS TO "COVERED OUTPATIENT DRUGS."

As a threshold matter, that CMS has taken the position Congress did not limit Medicaid coverage of outpatient drugs to "covered outpatient drugs" is dubious. The only support proffered for this proposition that directly addresses the issue are two letters

[8] 558 F.3d 903, 908-909 (9th Cir. 2009), citation omitted.
[9] 448 F.3d at 909, citations omitted.

from CMS in response to letters from the Utah Attorney General's Medicaid Fraud Control Unit.[10,11]

This correspondence was initiated by the Utah Attorney General's Office asking whether CMS interpreted the Medicaid statute as prohibiting Medicaid coverage of outpatient drugs that are not for a "medically accepted indication.[12] A letter responding to this question states, "(the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal regulations." [13] The letter is signed for the Director of the Center for Medicaid and State Operations by someone else, as follows: [14]



Incredulous with this response, the Utah Attorney General's Office wrote back:

> With all due respect, I beg to differ and direct your attention to Section 1927(k)(3) regarding a specific exception to the definition of "covered outpatient drug." In pertinent part it states that the term "covered outpatient drug" (which would otherwise be eligible for Medicaid Federal

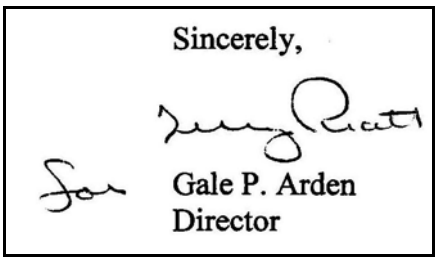
[10] Dkt. No. 91-4, also Dkt. No. 158-1, pp 12-17, included in *relator* PsychRights' written disclosure, which was unsealed by the Court at Dkt. No. 158.
[11] The Defendants also cite to two publications by CMS, Dkt. Nos. 93-2 & 93-3 neither of which address the question. Dkt. No. 93-2 mostly clarifies that in order for a non-approved use to be a "medically accepted indication" it has to be "supported," not just listed in one of the Compendia. It also states that the states are required to cover medically accepted indications, but says nothing about the propriety of seeking reimbursement for drugs that are not for a medically accepted indication and therefore excluded from the definition of "covered outpatient drug." Similarly, Dkt. No. 93-3 does not address the issue at hand. It concerns coverage for experimental drugs and
[12] Dkt. No. 158-1, pp 12 & 13.
[13] Dkt. No. 158-1, p. 14.
[14] *Id.*

> Financial Participation) **does not include "a drug or biological used for a medical indication which is not a medically accepted indication."**[15]

After addressing why the permissive language in 42 USC §1396r-8(d)(1)(B)(i) allowing states to restrict coverage to those that are for a medically accepted indication cannot override the specific prohibition contained in 42 U.S.C. § 1396r8 (k)(3), (6); 42 U.S.C. § 1396r-8 (g)(1)(B)(I), the Utah Attorney General's Office wrote:

> I strongly encourage you to run this issue by your legal counsel and am confident that they will conclude that the clear, unambiguous definition of "covered outpatient drug" means that States are eligible for Federal Financial Participation with respect to drugs that are reimbursed only for "medically accepted indications," i.e., only for uses either approved by the FDA or "supported" in the specified compendia.[16]

In response, without addressing the legal issues involved and without any indication CMS was following the interpretation of its legal counsel, a letter was sent back re-affirming the previous letter. [17] This letter is signed for the Director of the Center for Medicaid and State Operations, Disabled and Elderly Health Program Group, who is apparently a subordinate of the Director of the Center for Medicaid and State Operations over whose name the previous letter was issued, as follows: [18]



All four persons whose name appears on these two letters from CMS can thus claim the letter over their name was not written by him or her. It is therefore questionable whether these letters even represent the true position of Smith and Arden, let alone the formal position of CMS. In other words, it is very dubious that these letters

[15] Dkt. No. 158-1, p,15, emphasis in original.
[16] Dkt. No. 158-1, p. 16.
[17] Dkt. No. 158-1, p. 17.
[18] *Id.*

represent any sort of authorized interpretation of the statute by CMS. This is fatal to any deference at all.

III. EVEN IF CMS HAS TAKEN THE POSITION THAT CONGRESS DID NOT RESTRICT COVERAGE FOR OUTPATIENT DRUGS TO "COVERED OUTPATIENT DRUGS," THIS POSITION IS NOT ENTITLED TO *CHEVRON* DEFERENCE AND LITTLE, IF ANY *SKIDMORE* DEFERENCE

(A) The Text of the Statute is Clear from its Plain Language that Medicaid's Coverage of Outpatient Drugs is Restricted to "Covered Outpatient Drugs."

As set forth above, the first step in deference analysis is whether the "text in question is clear from the statute's plain language." As set forth above, 42 U.S.C 1396R-8(k)(3) provides, "The term 'covered outpatient drug' does not include any . . . drug . . . used for a medical indication which is not a medically accepted indication." The second definition of "coverage" in the American Heritage Dictionary, 4th Ed., is:

> 2. a. Inclusion in an insurance policy or protective plan.
> b. The extent of protection afforded by an insurance policy.[19]

Thus, the plain language of the text of the statute is that Congress restricted payment (coverage) under Medicaid for outpatient drugs to those that are for a medically accepted indication. This makes total sense. Congress made the policy decision that while it would not prohibit reimbursement for all "off-label" (non-FDA approved) uses, it would only allow Medicaid to pay for off-label uses that have a sufficient level of scientific support as documented in one or more of the Compendia.

Even if CMS has taken the position that Congress did not restrict coverage of outpatient drugs to "covered outpatient drugs," this interpretation is inconsistent with the plain language of the statute's text.[20]

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[19] Definition 8.b., of "cover" is "To protect by insurance."

[20] As mentioned in n. 11, supra., the defendants also cite to two CMS publications, reproduced at Dkt. Nos. 93-2 & 93-3 as representing CMS' interpretation. However, like the publications similarly asserted to be entitled to *Chevron* deference in *Northern California River Watch*, 2010 WL 332968, *10, at most, they address the issue only

(B) CMS Was Not Authorized to Promulgate a Rule that Medicaid Coverage for Outpatient Drugs Extends Beyond "Covered Outpatient Drugs," and the Letters Do Not Represent Rulemaking

Under *Mead*, as explicated most recently by the Ninth Circuit in *Northern California River Watch*, prior to moving to step two under *Chevron*, the Court must determine whether (1) Congress clearly delegated authority to CMS to make rules carrying the force of law, and (2) CMS' interpretation was promulgated in the exercise of that authority.[21]

(1) Congress Did Not Delegate Authority to CMS

Leaving aside that the text of the statute is clear from its plain language, the defendants did not cite to any statutory provision clearly authorizing CMS to promulgate a rule carrying the force of law allowing Medicaid to cover outpatient drug prescriptions that are not for a medically accepted indication.

(2) The Interpretation Was Not Promulgated In the Exercise of CMS's Authority.

Even if CMS has some sort of authority to interpret the statute through making a rule "carrying the force of law," the two letters from CMS to the Utah Attorney General's Office do not qualify. They were merely responses by CMS employees to an inquiry by the Utah Attorney General's office, and have none of the attributes of the type of "law making pretense" required under *Mead*[22] and *Marmolejo-Campos v. Holder*.[23,24] Even if the letters were authorized communications from CMS, they are far less of a law making nature than those found insufficient in *Mead* and *Marmolejo-Campo* to invoke *Chevron*

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tangentially and "therefore, have no 'power to persuade' [The Ninth Circuit] of any particular interpretation."

[21] 2010 WL 3329681 at *4.

[22] 533 U.S. 218, 232-233, 121 S.Ct. 2164.

[23] 558 F.3d 903, 908-909 (9th Cir. 2009), citation omitted.

[24] This is in stark contrast to the formal hearing process involved in *Alaska DHSS*.

deference. In fact, the letter which the defendants claim should be given deference disclaim any such lawmaking pretense:

> Section 1927 of the Social Security Act (the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal regulations.[25,26]

That the agency decision at issue in *Marmolejo-Campo* was not published was dispositive in the Ninth Circuit's holding that it is not to be given *Chevron* deference. Here, the CMS letters are not even a decision. They were also very non-public until PsychRights tracked the correspondence down after reading the Pharmalot blog of September 15, 2008, titled "Antipsychotics & State Lawsuits: Stallard Explains."[27]

(C) The Interpretation That Congress Did Not Limit Covered Outpatient Drugs to "Covered Outpatient Drugs" is Unreasonable.

Frankly, PsychRights and Griffin believe *Chevron* deference has already been defeated at step one, but step two of *Chevron* deference analysis is whether the agency's interpretation of the statute is "a reasonable policy choice for the agency to make."[28] PsychRights and Griffin respectfully suggest it is an unreasonable policy choice for CMS to decide Medicaid will cover any outpatient prescription in spite of such use not having the requisite level of scientific support that Congress decreed for "covered outpatient drugs."

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[25] Dkt. No. 158-1, p.14.
[26] It seems worth noting that "coverage" is used here as commonly understood to mean what is included, or the extent of, protection under an insurance plan.
[27] http://www.pharmalot.com/2008/09/antipsychotics-state-lawsuits-stallard-explains/, last accessed on September 20, 2010.
[28] *Chevron*, 467 U.S. at 845.

(D) Little, if Any Deference is Warranted Under *Skidmore*.

As the Ninth Circuit recently reiterated in *Marmolejo-Campos*, even though *Chevron* deference is not warranted, some level of deference under *Skidmore* may still be applicable:[29]

> Nevertheless, *Skidmore* deference remains "intact and applicable" when an agency with rulemaking power interprets its governing statute without invoking such [rule making] authority. Under *Skidmore*, the measure of deference afforded to the agency varies "depend[ing] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."[30]

Leaving aside that the purported CMS interpretation may not even be the position of CMS, PsychRights and Griffin respectfully suggest that if it is to be treated as the official position of CMS, it is entitled to little or no deference under *Skidmore*: there was only cursory consideration, the reasoning is defective, there are no other statements that have been identified consistent with these letters, and the position is unpersuasive.

Perhaps most importantly, in False Claims Act cases against drug companies, the Department of Justice has subsequently taken exactly the opposite view of that purported to be the position of CMS. In September of 2009, the Department of Justice issued a news release announcing a $2.3 Billion settlement with Pfizer, stating, "[Pfizer] caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs."[31] Similarly, the Government's February 13, 2009, Complaint in Intervention in *U.S. ex rel Gobble v. Forest Laboratories*, Case No. 03-cv-10395-NMG, District of Massachusetts, states that prescriptions presented to Medicaid that are not for medically accepted indications are false claims.[32] To the same effect is the settlement agreement in *U.S. ex*

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[29] 2010 WL 3329681 at *4.
[30] 558 F.3d at 910.
[31] Dkt. No. 108-1, p.1.
[32] Dkt. No. 108-2, pp. 8-9, at ¶s 26-30; p. 10, ¶37; p. 31 ¶97; p. 32, ¶100.

rel Wetta v. AstraZeneca Pharmaceuticals, Case No. 04-cv-3479-BMS, Eastern District of Pennsylvania.[33]

Most recently, *ex rel Gobble*, described above, and other False Claims Act cases against Forest Laboratories for causing false claims by promoting the use of the psychotropic drugs Celexa and Lexapro[34] for use in children and youth when there were no medically accepted indications for use in children and youth was recently settled for $149 million, and Forest agreed to pay an additional $150 million fine in conjunction with pleading guilty to criminal conduct. As stated in the Settlement Agreement:

> 1. During the period January 1998 through December 2005, Forest knowingly caused false or fraudulent claims for Celexa and Lexapro to be submitted to the Federal Health Care Programs by promoting the sale and use of Celexa and Lexapro to physicians for pediatric uses (including by disseminating false and misleading information about the safety and efficacy of Celexa and Lexapro in treating pediatric patients), as set forth in the United States Complaint in Intervention, when those uses were not approved by the Food and Drug Administration ("FDA"), were not medically accepted indications (as defined by 42 U.S.C. § 1396r-8(k)(6)), and were not covered by Federal Health Care Programs [including Medicaid].

Exhibit 1, page 4.

Both cases cited by the defendants for the proposition that the Department of Justice's interpretation of the statute should be afforded no deference, *Citizens for Responsibility* and *American Civil Liberties Union of N. Cal.*, involve cases in which the Department of Justice was resisting providing documents under the Freedom of Information Act, i.e., the Department of Justice was, itself, a party. Here, not only has the Department of Justice consistently taken the position asserted by *relators* PsychRights and Griffin, but the drug company defendants in these cases have agreed to pay billions of dollars to settle False Claims Act actions based on the same interpretation.

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[33] Dkt. No. 108-3, p.6.
[34] And one non-psychotropic drug for any use.

Where, as here, two employees of CMS sign letters for two other CMS employees, in non-public correspondence responding to a query about Medicaid coverage, asserting the exact opposite interpretation than its legal counsel, apparently without consultation with legal counsel after being advised to do so, little or no *Skidmore* deference should be given.

IV. CONCLUSION

For the foregoing reasons, *Chevron* deference is unwarranted and no *Skidmore* deference should be given to the alleged position of CMS that Congress did not limit Medicaid coverage of outpatient drugs to "covered outpatient drugs."

RESPECTFULLY SUBMITTED this 21st day of September, 2010.

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