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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

UNITED STATES OF AMERICA)	
<i>Ex rel.</i> Law Project for Psychiatric)	Case No. 3:09-CV-00080-TMB
Rights, an Alaskan non-profit)	
corporation,)	
)	
Plaintiff,)	
)	
vs.)	
)	
OSAMU H. MATSUTANI, MD, <i>et al.</i> ,)	
)	
Defendants.)	
_____)	

**MOTION TO REQUIRE DEFENDANT THOMSON REUTERS
(HEALTHCARE) TO PROVIDE PSYCHRIGHTS WITH DRUGDEX
ENTRIES**

Qui tam relator Law Project for Psychiatric Rights (PsychRights®) moves for an order requiring defendant Thomson Reuters (Healthcare), hereinafter "Thomson," to provide PsychRights with full, current, electronic copies of the following DRUGDEX entries:

- | | |
|---|----------------------------------|
| 1. Abilify (Aripiprazole) | 5. Depakote (valproic acid) |
| 2. Adderall
(amphetamine/dextroamphetamine) | 6. Desyrel (trazadone) |
| 3. Concerta (methylphenidate) | 7. Dexadrine (dextroamphetamine) |
| 4. Cymbalta (duloxetine) | 8. Effexor (venlafaxine) |
| | 9. Haldol (haloperidol) |

- | | |
|-------------------------------|--------------------------------|
| 10. Invega (paliperidone) | 17. Symbyax (fluoxetine |
| 11. Lamictal (lamotrigine) | hydrochloride/olanzapine) - |
| 12. Lexapro (escitalopram) | 18. Tegretol (carbamazepine) |
| 13. Neurontin (gabapentin) | 19. Tofranil (imipramine) |
| 14. Risperdal (risperidone) | 20. Trileptal (oxcarbazepine) |
| 15. Ritalin (methylphenidate) | 21. Vyvanse (lisdexamfetamine) |
| 16. Seroquel (quetiapine) | 22. Zyprexa (olanzapine) |

I. DISCUSSION

On March 24, 2010, at Dkt. No. 78, PsychRights filed a Motion for Preliminary Injunction Against Defendants Hogan and Streur to prohibit them, their agents, servants, employees and attorneys, and any persons who are in active concert or participation with them, from committing Medicaid Fraud by presenting claims or causing claims to be presented to Medicaid for reimbursement or payment of the United States Government's federal financial participation (FFP) share¹ of outpatient prescriptions for psychotropic drugs to recipients under the age of 18 (children and youth) that are not for a medically accepted indication (Motion for Preliminary Injunction).

On March 26, 2010, at Dkt. No. 79, this Court issued an Order Denying Motion for Preliminary Injunction Without Prejudice (Order), because the exhibits were not numbered in accordance with Local Rule 10.1(c), and provided at page 4:

Finally, it appears that some of the exhibits are incomplete and will need to be re-scanned. For example, all of the sentences in Exhibit E.32 (pages 1-78) are cut off on the right side, suggesting that there is more information which is not included in this exhibit. Upon refile, Plaintiff shall ensure that the text in all of its exhibits is complete and legible.

The reason why those exhibits were cut off on the right side is that the copies PsychRights had managed to acquire came that way. The reason why PsychRights is seeking these documents from Thomson is that Thomson closely guards access to DRUGDEX entries and they are very difficult or expensive to acquire, or both. Ex. 1, pp.

¹ "FFP" stands for "Federal Financial Participation," which means "the Federal Government's share of a State's expenditures under the Medicaid program." 42 CFR §400.203.

1, 2 & 5. In fact, Thomson, claims these DRUGDEX entries are confidential. Ex. 1, p. 1. This seems extraordinary since Congress designated DRUGDEX as one of the compendia to which reference is to be made to determine whether an off-label use² is a medically accepted indication and therefore covered by Medicaid.³

The reason why PsychRights did not just serve a discovery request and this motion is required is that, as reflected in the Parties' First Scheduling and Planning Conference Report, Dkt. No. 62 (First Scheduling Report), during the parties' F.R.C.P 26(f) Conference, the parties agreed no initial disclosures would be required, or discovery take place without leave of the court until June 30, 2010. Dkt. No. 62, p. 2., ¶¶1.1 & ¶1.3. Even though the Court has not entered an Order implementing the First Scheduling Report, *see*, Dkt. No. 62-2, PsychRights does not feel it can just initiate discovery without leave of the Court.

PsychRights first started trying to obtain current, uncut off, versions of the DRUGDEX entries from Thomson on March 13, 2010. Ex. 1, p. 5. Following the March 26, 2010, Order, PsychRights renewed its request to Thomson to voluntarily provide current, uncut off DRUGDEX entries for the drugs listed above. Ex. 1, pp. 2-3. On Sunday, March 28, 2010, in an e-mail that was apparently inadvertently copied to counsel for PsychRights, Mr. James Rittinger, New York counsel for Thomson, wrote Jim

² "Off-label use" means for an indication not approved by the Food and Drug Administration (FDA).

³ Congress restricted reimbursement for outpatient drugs by the federal government under Medicaid to those that are "medically accepted indications," defined as indications approved by the FDA, or the use of which is supported by one or more citations included or approved for inclusion in (i) American Hospital Formulary Service Drug Information, (ii) United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System. 42 USC § 1396r-8(k)(3); 42 USC § 1396r-8(k)(6); 42 USC § 1396r-8(g)(1)(B)(i); *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass 2008); *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp. 2d 39, 44,45 (D.Mass 2001).

Togerson, local counsel for Thomson, "We can talk tomorrow but we don't want to give him anything." Ex. 1, p.3.⁴

The reason why the DRUGDEX entries are so important to the question of what is or is not a medically accepted indication is it is universally recognized that "Drugdex's listings are wider than those of the other two directories." Ex. 2, p. 1. Thus, as a practical matter, it is DRUGDEX which must be consulted to determine what off-label uses are "medically accepted indications" and therefore covered under Medicaid.

Through its systematic review of the DRUGDEX entries PsychRights has been able to acquire, PsychRights has developed and updates as new information is acquired, a Medically Accepted Indications Chart for specific psychotropic drugs administered to children and youth. Ex. 1, pp 7-10.⁵ In PsychRights' view, in order for an off-label use to be "supported by" a DRUGDEX citation and therefore a "medically accepted indication," in the Medically Accepted Indication Chart, it must have a Class I or Class IIa "Recommendation Rating." *See*, Ex. 1, p. 11 for the DRUGDEX Recommendation, Evidence and Efficacy Ratings. The cut off DRUGDEX entries that were included in Exhibit E to PsychRights' March 24, 2010, Motion for Preliminary Injunction all included the Recommendation Rating so were sufficient for the purpose for which they were attached, even though some of the words on the right margin were cut off.

PsychRights certainly desires to attach complete documents, and as set forth above, tried to obtain them prior to filing its March 24, 2010, Motion for Preliminary Injunction. Being unsuccessful in obtaining them, however, PsychRights filed what it had because the Recommendation Ratings are all included, and it views any indication receiving a Recommendation Rating below IIa as not being "supported by" DRUGDEX. However, this Court has rejected the exhibits of the DRUGDEX entries which have text

⁴ As required by Alaska Rule of Professional Conduct §4.4(b), counsel for PsychRights promptly notified Thomson's counsel he had received the communication. Exhibit 1, p. 3.

⁵ This is the version of the Medically Accepted Indication Chart to which the March 13, 2010, e-mail, Ex. 1. p. 5, refers.

cut off on the right and ordered PsychRights to file complete and legible copies, which is the occasion for this motion.

Because the default set by Congress is that off-label indications are not covered by Medicaid, it is the obligation of those who would assert such uses are nonetheless medically accepted indications, such as defendants Hogan, Struer, Sandoval and McComb; the psychiatrist and agency defendants; and the pharmacy defendants, to provide the proof that such indications are "supported by" one or more of the Compendia. Thus, PsychRights can proceed with refileing its motion for preliminary injunction in compliance with this Court's March 26, 2010, Order by simply eliminating references to the drugs for which PsychRights does not have uncut off versions. This is a suboptimal approach, however, and PsychRights believes this situation constitutes good cause for this Court to order Thomson to simply provide current, electronic, uncut off versions.

II. CONCLUSION

For the foregoing reasons PsychRights' motion to provide PsychRights with the above listed DRUGDEX entries should be granted.

RESPECTFULLY SUBMITTED this 29th day of March, 2010.

Law Project for Psychiatric Rights, an Alaskan non-profit corporation

By: /s/ James B. Gottstein
JAMES B. GOTTSTEIN
ABA #7811100

Attorney for *relator*, Law Project for Psychiatric Rights

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 29, 2010, a true and correct copy of this document and accompanying proposed order was served electronically on all parties of record by electronic means through the ECF system as indicated on the Notice of Electronic Filing, or if not confirmed by ECF, by first class regular mail.

/s/ James B. Gottstein

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Law Project for Psychiatric Rights