Subject: Re: Request for DRUGDEX Entries
From: Jim Gottstein <jim.gottstein@psychrights.org>
Date: Sun, 28 Mar 2010 20:59:27 -0800
To: "Torgerson, James E." <JETORGERSON@stoel.com>
CC: jrittinger@ssbb.com, tcahill@ssbb.com, Jim Gottstein <jim.gottstein@psychrights.org>

Hi Jim,

On 3/28/2010 8:05 PM, Torgerson, James E. wrote:

> Jim:
>
> As to those of your representations about which I have knowledge, I believe your e-mail is a fair summary.
>
> I do have a different perspective, however, as to the merits of your motion for preliminary injunction and, more specifically, as to the appropriateness of PsychRights seeking to compel Thomson Reuters's confidential information. I will defer that discussion for later, except to note that it appears that the motion you propose to file would be in violation of the Court-ordered stay on discovery.
>
> > "With respect to preliminary discovery, except as set forth below, the parties further agree that initial disclosures shall not be due, and **the parties shall not make any discovery requests prior to Wednesday, June 30, 2010.** Plaintiff reserves the right to make discovery requests that are limited to matters raised by Defendants' responses to the complaint. Defendants' reserve the right to object to any such discovery requests that allegedly address matters raised by the Defendants' responses to the complaint." (*Bold in original*)
>
> Unless I misunderstand the Court's Order, I believe the motion you threaten to file against Thomson Reuters is precluded until no sooner than June 30, 2010.

I don't believe the Court signed the Order, but I do feel honor bound to abide by the agreement we made, §1.3 of which provides:

> 1.3. Variation. Upon motion, for good cause, the parties agree any party may seek variation of the terms hereof.

I believe such good cause exists.

I also think it is interesting that Thomson claims DRUGDEX entries are confidential when Congress designated DRUDEX as one of the sources by which medically accepted indications are to determined.

> Regards,
>
> Jim
>
> **James E. Torgerson**
> **STOEL RIVES LLP** | 510 L Street, Suite 500 | Anchorage, AK 99501-1959
> Direct: (907) 263-8404 | Reception: (907) 277-1900 | Fax: (907) 277-1920

jetorgerson@stoel.com | www.stoel.com

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Sunday, March 28, 2010 2:49 PM
To: Torgerson, James E.
Cc: jrittinger@ssbb.com; tcahill@ssbb.com; Jim Gottstein
Subject: Request for DRUGDEX Entries

Hi Jim,

In order to comply with Local Rule 7.2(c)(1)[A](ii) & (iii), this is to summarize and memorialize PsychRights' efforts to obtain current and untruncated DRUGDEX entries for specific drugs.

Just over two weeks ago, on March 13, 2010, in anticipation of PsychRights filing a motion for preliminary injunction in which updated DRUGDEX entries would be desirable, I wrote you in the (hopefully) attached e-mail requesting that your client, Thomson Reuters (Healthcare), the publisher of DRUGDEX, provide PsychRights with updated entries for the drugs in PsychRights' Medically Accepted Indication Chart, plus 9 other drugs, mostly benzodiazepines. On March 18, you called and asked why I wanted them and what benefit would accrue to your client to give them to me.

With respect to the first question, I responded that acquiring DRUGDEX entries was very difficult, or expensive, or both, and that I wanted updated versions for a prospective motion for preliminary injunction. With respect to the second question, I suggested that I thought I would be entitled to them if I went to the court to ask for them, and that your client might wish to avoid looking bad to the court by refusing to provide them without forcing me to go to the court, and that it would save your client the attorney's fees involved in litigating the issue, although I surmised that was probably insignificant to your client. You said you would get back to me.

Not having heard back almost a week later, on March 24, 2010, I went ahead and filed the motion for preliminary injunction with the versions I had. On March 26, 2010, the court rejected the motion without prejudice to refiling because the exhibit numbering did not conform to the Local Rules and many of the DRUGDEX entries were truncated on the right side. Thus, in order to comply with the Court's order regarding the exhibits, I need to have untruncated versions.

I went through the DRUGDEX entries for the 33 drugs reviewed for the preliminary injunction motion and determined I need the entries for the following drugs in order to be able to include all of 33 them in a renewed motion for preliminary injunction in compliance with the Court's March 26, 2010, Order:

1. Abilify (Aripiprazole)
2. Adderall (amphetamine/dextroamphetamine)

Exhibit 1, page 2

3. Concerta (methylphenidate)
4. Cymbalta (duloxetine)
5. Depakote (valproic acid)
6. Desyrel (trazadone)
7. Dexadrine (dextroamphetamine)
8. Effexor (venlafaxine)
9. Haldol (haloperidol)
10. Invega (paliperidone)
11. Lamictal (lamotrigine)
12. Lexapro (escitalopram)
13. Neurontin (gabapentin)
14. Risperdal (risperidone)
15. Ritalin (methylphenidate)
16. Seroquel (quetiapine)
17. Symbyax (fluoxetine hydrochloride/olanzapine)
18. Tegretol (carbamazepine)
19. Tofranil (imipramine)
20. Trileptal (oxcarbazepine)
21. Vyvanse (lisdexamfetamine)
22. Zyprexa (olanzapine)

Earlier today I e-mailed you, copying Thomson's New York attorneys, asking if Thomson would provide me copies by noon tomorrow so I wouldn't have to go to the Court. Apparently inadvertently copying me, Thomson's New York counsel e-mailed you, "We can talk tomorrow but we don't want to give him anything."

If I have mischaracterized anything or you have a different perspective, please let me know.

--

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President/CEO

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The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of forced psychiatric drugging. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and

> subjected to other brain and body damaging interventions against their will. Extensive information about this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

--

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Subject: Updated DRUGDEX Monographs
From: Jim Gottstein <jim.gottstein@psychrights.org>
Date: Sat, 13 Mar 2010 12:23:46 -0900
To: jetorgerson@stoel.com
CC: Jim Gottstein <jim.gottstein@psychrights.org>

Hi Jim,

I am working on a motion for a preliminary injunction I expect to file shortly after everyone's responses to the complaint are in and in working through that it has become apparent the most recent DRUGDEX® monographs are extremely relevant. For example, the FDA approved Seroquel and Zyprexa for limited pediatric uses on December 4, 2009, which is not reflected in the DRUGDEX monographs I have. The injunction which I will be seeking would, of course, not prohibit causing or presenting claims to Medicaid for those newly approved indications. Additions to medically accepted indications as a result of new FDA approval is easy enough for me to pick up, but DRUGDEX also updates its monographs pertaining to indications that have not received FDA approval.

It seems likely the judge would order your client to provide them in the context of the motion for preliminary injunction and I can certainly subpoena them to a hearing (subject to your possible objection), but I would prefer not to have to go to the court. Therefore, I am writing to ask if your client would voluntarily provide me with copies of the most recent monographs, and updates as they occur, for the drugs included in the Medically Accepted Indications Chart, plus the following drugs which I intend to add to the chart:

- alprazolam (Xanax®)
- Clonazepam (Klonopin®)
- clorazepate (Tranxene®)
- diazepam (Valium®)
- flurazepam (Dalmane®)
- lorzepam (Ativan®)
- temazepam (Restoril®)
- zaleplon (Sonata®)
- Zolpidem (Ambien®)

Granting me access to DRUGDEX would certainly be acceptable to me and presumably easier for your client, but I know your client closely guards access to DRUGDEX. Perhaps your client can grant me access to just the drugs of interest. Again, these would be the drugs included in the Medically Accepted Indications Chart as well as those listed above.

Please let me know.
--

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Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by The Law Project for Psychiatric Rights (PsychRights

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Key:	White Background: Medically Accepted Indication			
	Orange Background: Pediatric Indication cited, but not supported by DRUGDEX			
	Red Background: No Pediatric FDA Approval or DRUGDEX citation			
Abilify (Aripiprazole) - Antipsychotic				
	Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes	Yes (for 10 yrs old and up)		
	Bipolar I Disorder, monotherapy, Manic or Mixed Episodes	Yes (for 10-17 years old re acute therapy)		
	Schizophrenia	Yes (for 13-17 years old)		
Adderall (amphetamine/dextroamphetamine) - Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years old and up re: [immediate-release] and 6 years old and up re: [extended-release] drug		
	Narcolepsy	Yes (for 6 years old and up re: [immediate release] drug)		
Anafranil (clomipramine) - Antidepressant; Antidepressant, Tricyclic; Central Nervous System Agent				
	Depression	No		Class IIb
	Obsessive-Compulsive Disorder	Yes (for 10 years and up)		
Clorazil (clozapine) – Antipsychotic; Dibenzodiazepine				
	Bipolar I Disorder	No		Class IIb
	Schizophrenia, Treatment Resistant	No		cited, with no recommendation level
Concerta (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old to 12 years old)		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up) re ConcertaR		
	Autistic Disorder	No		Class IIb
	Impaired Cognition - inding related to coordination/ in coordination	No		Class IIb
	Schizophrenia	No		Class IIII
	Traumatic Brain Injury	No		Class IIb
Cymbalta (duloxetine) - Antidepressant; Central Nervous System Agent; Neuropathic Pain Agent; Serotonin/Norepinephrine Reuptake Inhibitor				
Depakote (valproic acid) – Anticonvulsant; Antimigraine; Valproic Acid (class)				
	Absence Seizure, Simple and Complex and/or Complex Partial Epileptic Seizure	Yes (10 years and older)		
	Mania	No		Class IIII
	Mental Disorder - Mood Disorder	No		Class IIb
	Chorea	No		Class IIb

Any errors in this document should be brought to the attention of Jim Gottstein at PsychRights.Org
Jim.Gottstein@PsychRights.Org, Tel. (907) 274-7686, Fax (907) 274-9493

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Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Dexedrine (dextroamphetamine) - Amphetamine (class); CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years to 16 years old (immediate-release) and age 6 years to 16 years old (sustained-release))		
	Narcolepsy	Yes (for 6 years old and up)		
Desyrel (*trazadone*) - Antidepressant; Triazolopyridine				
Effexor (venlafaxine) – Antidepressant; Antidepressant, Bicyclic; Phenethylamine (class); Serotonin/ Norepinephrine Reuptake Inhibitor				
	Attention Deficit Hyperactivity Disorder (ADHD)	No		Class IIb
	Generalized Anxiety Disorder	No		Class IIb
	Major Depressive Disorder	No		Class IIb
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		
	Social Phobia	No		Class IIb
Focalin (dexmethylphenidate) - Amphetamine Related; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years and older)		
Geodon (ziprasidone) - Antipsychotic; Benzisothiazoyl				
Haldol (haloperidol) - Antipsychotic; Butyrophenone; Dopamine Antagonis				
	Agitation	No		Class IIb
	Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy	Yes (for 3 years old and up)	It does not appear the injectible form (decanoate) is FDA approved for any pediatric use. DRUGDEX says safety and efficacy not established.	
	Problematic Behavior in Children (Severe), With failure to respond non-antipsychotic medication or psychotherapy	Yes (for 3 years old and up)		
	Psychotic Disorder	Yes (for 3 years old and up but ORAL formulations only)		
	Schizophrenia	Yes (for 3 years old and up but ORAL formulations only)		
Invega (paliperidone) - Antipsychotic; Benzisoxazole				
Lamictal (lamotrigine) - Anticonvulsant; Phenyltriazine				
	Bipolar Disorder, Depressed Phase	No		Class IIb
	Epilepsy, Refractory	No	Class IIa	
Lexapro (escitalopram)- Antianxiety, Antidepressant, Serotonin Reuptake Inhibitor				
	Major Depressive Disorder	Yes (for 12 years old and up)		
Luvox (fluvoxamine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Asperger's Disorder	No		Class IIb
	Obsessive-Compulsive Disorder	Yes (for 8 years old and up and immediate release formula only)		
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		

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Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Mellaril (thioridazine) - Antipsychotic; Phenothiazine; Piperidine				
	Behavioral Syndrome	No		Class IIII
	Schizophrenia, Refractory	Yes		
Orap (pimozide) - Antipsychotic; Diphenylbutylpiperidine; Dopamine Antagonist				
	Gilles de la Tourette's syndrome	Yes (12 years and older)		
	Anorexia Nervosa	No		Class III
Paxil (paroxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
Prozac (fluoxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Anxiety Disorder of Childhood	No		Class IIb
	Major Depressive Disorder	Yes (for 8 years old and up)		
	Obsessive-Compulsive Disorder	Yes (for 7 years old and up		
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		
Ritalin (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years to 12 years old)(exteded release)		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)(immediate release)		
	Narcolepsy	Yes (for 6 years and up, and Ritalin(R) -SR only)		
	Schizophrenia	No		Class IIII
	Traumatic Brain Injury	No		Class IIb
Risperdal (risperidone) - Antipsychotic; Benzisoxazole				
	Autistic Disorder – Irritability	Yes (for 5 years old and up)		
	Bipolar I Disorder	Yes (for 10 years old and up)		
	Schizophrenia	Yes (for 13 years old and up, ORALLY)		
Seroquel (QUETIAPINE) - Antipsychotic; Dibenzothiazepine				
	Manic episodes associated with bipolar disorder	Yes, 10-17 (12/4/09)		
	Schizophrenia	Yes 13-17 (12/4/09)		
	Schizophrenia	Not prior to 12/4/09		Class IIb
Sinequan (doxepin) - Antianxiety Antidepressant; Antidepressant, Tricyclic; Antiulcer Dermatological Agent				
	Alcoholism - Anxiety – Depression	Yes (for 12 years old and up)		
	Anxiety – Depression	Yes (for 12 years old and up)		
	Anxiety - Depression - Psychoneurotic personality disorder	Yes (for 12 years old and up)		

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Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by The Law Project for Psychiatric Rights (PsychRights

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Strattera (atomoxetine) - Central Nervous System Agent; Norepinephrine Reuptake Inhibitor				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)		
	Attention Deficit Hyperactivity Disorder (ADHD) - Social phobia	No		Class IIb
Symbyax (fluoxetine hydrochloride/olanzapine) - Antidepressant; Antipsychotic				
Tegretol (carbamazepine) - Anticonvulsant; Antimanic; Dibenzazepine Carboxamide; Neuropathic Pain Agent				
	Epilepsy, Partial, Generalized, and Mixed types	Yes		
	Migraine; Prophylaxis			Class IIb
	Neuropathy, General			Class IIb
Tofranil (imipramine) - Antidepressant; Antidepressant, Tricyclic; Urinary Enuresis Agent				
	Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type	No		Class IIb
	Depression	No		Class IIb
	Nocturnal enuresis	Yes (for 6 years old and up)		
	Separation Anxiety Disorder of Childhood	No		Class IIII
	Schizophrenia, Adjunct	No		Class IIII
Trileptal (*oxcarbazepine*) - Anticonvulsant; Dibenzazepine Carboxamide				
	Partial Seizure, monotherapy	Yes (for 4 years old and up)		
	Partial seizure; Adjunct	Yes (for 2 years old and up)		
Vyvanse (lisdexamfetamine) - Amphetamine (class); CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old to 12 years)		
Zoloft (sertraline) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Obsessive-Compulsive Disorder	Yes (6 years old and up)		
	Anorexia nervosa	No		Class IIII
	Generalized Anxiety Disorder	No		Class IIb
	Major Depressive Disorder	No		Class IIb
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		
Zyprexa (olanzapine) - Antipsychotic; Thienobenzodiazepine				
	Schizophrenia	Yes (ages 13-17), approved 12/4/09		
	manic or mixed episodes associated with bipolar I disorder	Yes (ages 13-17), approved 12/4/09		
	Bipolar 1, Disorder, Acute Mixed or Manic Episodes	Not prior to 12/4/09	Class IIa	
	Schizophrenia	Not prior to 12/4/09		Class IIb
	Schizophrenia, Refractory	Not prior to 12/4/09		Class IIb
	Pervasive Developmental Disorder	No		Class IIb
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		

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DRUGDEX® Consults

RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS

RESPONSE

The Thomson Efficacy, Strength of Evidence and Strength of Recommendation definitions are outlined below:

Table 1. Strength Of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminant	Evidence Inconclusive	

Table 2. Strength Of Evidence	
Category A	Category A evidence is based on data derived from: Meta-analyses of randomized controlled trials with homogeneity with regard to the directions and degrees of results between individual studies. Multiple, well-done randomized clinical trials involving large numbers of patients.
Category B	Category B evidence is based on data derived from: Meta-analyses of randomized controlled trials with conflicting conclusions with regard to the directions and degrees of results between individual studies. Randomized controlled trials that involved small numbers of patients or had significant methodological flaws (e.g., bias, drop-out rate, flawed analysis, etc.). Nonrandomized studies (e.g., cohort studies, case-control studies, observational studies).
Category C	Category C evidence is based on data derived from: Expert opinion or consensus, case reports or case series.
No Evidence	

Table 3. Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective
Class IIa	Evidence Favors Efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is Inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective.