IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation, Plaintiff, vs. STATE OF ALASKA, *et al.*, Defendants,	)

Case No. 3AN 08-10115CI

OPPOSITION TO MOTION TO STAY DISCOVERY

Plaintiff, the Law Project for Psychiatric Rights (PsychRights®), opposes the Motion to Stay Discovery (Motion for Stay) filed by defendants State of Alaska, *et al.*, (State). The Motion for Stay seeks a stay of all discovery pending determination of the State's contemporaneously filed Motion for Judgment on the Pleadings.

The State's Motion for Stay is fundamentally flawed in two respects. First, the burden and expense of the subject discovery does not outweigh its immense benefit to Alaskan children and youth. The evidence is overwhelming that current pediatric prescribing practices are improvident, largely ineffective, extremely harmful, and non-pharmacological approaches are far better. The evidence sought to be obtained regards the actual practice of pediatric psychopharmacology to Alaskan children and youth in State custody and through Medicaid, and the extent of the harm being done. The planned discovery is anticipated to produce evidence entitling PsychRights to one or more preliminary injunctions and at least partial summary judgment as to declaratory relief. The harm being done to Alaskan children and youth should not be extended because of a stay of discovery. Contrary to the State's abdication of responsibility in its Motion for

Judgment on the Pleadings, it has the affirmative duty to protect the safety of children and youth in its custody. The fulfillment of this duty should not be further delayed.

Second, contrary to the State's assertion, the pending Motion for Judgment on the Pleadings is not likely to dispose of the entire case. The sole legal basis asserted is lack of standing, which is in itself unmeritorious and in any event, can be addressed by naming additional plaintiffs. In addition, the Motion for Judgment on the Pleadings complains about a lack of specificity in the Amended Complaint and goes outside the pleadings. Under such circumstances discovery must be allowed to proceed.

I. The Standards for Staying Discovery

In support of its Motion for Stay the State argues that a stay of discovery is within the discretion of the Court and appropriate pending determination of a dispositive motion, citing to the Alaska case of *Karen L. v. State Dept. of Health and Social Services, Div. of Family and Youth Services,*[1] and some federal cases.

However, *Karen L.* is completely inapplicable because it involves the situation where government officials were sued personally and not, as here, in their official capacity. In *Karen L.*, the question was whether discovery could be stayed pending a determination of official immunity. PsychRights found no other Alaska cases concerning when or under what circumstances a stay of discovery might be warranted and the State cited none in their motion. However, the federal cases cited by the State do not support its position that discovery should be stayed here.

[1] 953 P.2d 871, 879 (Alaska 1998).

In *Chavous v. District of Columbia Financial Responsibility and Management Assistance*,[2] the district court held:

> A trial court "ordinarily should not stay discovery which is necessary to gather facts in order to defend against [a] motion [to dismiss]." ("discovery should precede consideration of dispositive motions when the facts sought to be discovered are relevant to consideration of the particular motion at hand.").[3]

In *Williamson v. U.S. Dept. of Agriculture*,[4] also cited by the State, the Fifth Circuit held "if discovery could uncover one or more substantial fact issues, appellant was entitled to reasonable discovery to do so," and that in such circumstances a stay of discovery would be an abuse of discretion.

The cases cited by the State have reviewed and considered the specific discovery requests and determined there was no prejudice in staying discovery.[5] Here, the State seeks a blanket stay of discovery without showing any of the discovery is in any way unwarranted, or even burdensome, let alone that it would not lead to evidence that might be relevant to the Motion for Judgment on the Pleadings.[6] As will be shown below, the

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[2] 201 F.R.D. 1, 3 (D.D.C., 2001).
[3] Citation omitted.
[4] 815 F.2d 368, 373 (C.A.5 1987).
[5] *Karen L. v. State Dept. of Health and Social Services, Div. of Family and Youth Services*, 953 P.2d 871, 879 (Alaska 1998); *Schism v. U.S.*, 316 F.3d 1259, 1300 (C.A.Fed.2002); *Brazos Valley Coalition for Life, Inc. v. City of Bryan*, 421 F.3d 314, 327 (C.A.5 2005); *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1096 (C.A.D.C. 1996); *Chavous v. District of Columbia Financial Responsibility*, 201 F.R.D. 1 (D.D.C. 2001).
[6] Since the dispositive motion is one for judgment on the pleadings pursuant to Civil Rule 12(c), the presumption is that discovery would not be relevant. However, the State's Motion for Judgment on the Pleadings goes outside the pleadings. In addition, the Motion for Judgment on Pleadings complains about a lack of specificity in the Amended Complaint and the discovery PsychRights will be seeking can supply such specificity.

discovery requested to date is extremely modest and PsychRights has fashioned a focused discovery plan proceeding in a logical order. Delaying discovery will lengthen the time that Alaskan children and youth will not have the opportunity to have a motion for preliminary injunction filed on their behalf and a delay of much time could be very counterproductive by necessitating broader, less focused and less ordered discovery requests in order to get it done before the trial date.

Ultimately, as the district court in *Chavous* noted:

> In the determination of whether to stay discovery while pending dispositive motions are decided, the trial court "inevitably must balance the harm produced by a delay in discovery against the possibility that [a dispositive] motion will be granted and entirely eliminate the need for such discovery."[7]

This seems right and to the extent the Motion for Judgment on the Pleadings is decided soon, the prejudice will be lessened. But what if the State files a series of motions it characterizes as "dispositive?"

The Motion for Judgment on the Pleadings, while it includes inaccurate and extraneous statements of counsel regarding factual matters, is legally grounded entirely on the extremely dubious contention that PsychRights lacks standing under Alaska's liberal standing requirements. This seems clearly rejected under *Trustees for Alaska v. State of Alaska*[8] and its progeny.

However, PsychRights can not safely ignore the unsupported assertions of counsel contained in the Motion for Judgment on the pleadings, and thus under the authority cited

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[7] *Id.*
[8] 736 P.2d 324 (Alaska 1987).

by the State, as set forth above, it is necessary to discuss the merits and the evidence PsychRights seeks in discovery.

II. The Merits

In this action, PsychRights seeks declaratory and injunctive relief that Alaskan children and youth have the right to prevent defendants from authorizing the administration of or paying for the administration of psychotropic drugs to them unless and until:

(i) evidence-based psychosocial interventions have been exhausted,

(ii) rationally anticipated benefits of psychotropic drug treatment outweigh the risks,

(iii) the person or entity authorizing administration of the drug(s) is fully informed of the risks and potential benefits, and

(iv) close monitoring of, and appropriate means of responding to, treatment emergent effects are in place.[9]

The State's defense is revealed in its Motion for Judgment on the Pleadings, and consists of the complete abdication of responsibility:

> [The defendants] have no meaningful ability to remedy the conduct alleged or administer the relief requested".[10]

Without getting far into the legal analysis here, the State's position is untenable. At a minimum, once the State has taken custody of a child or youth, the United States Supreme Court has held if the State,

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[9] *See*, ¶1 of Amended Complaint and §A of PsychRights' Prayer for Relief.
[10] Motion for Judgment on the Pleadings, page 20.

> fails to provide for his basic human needs-e.g., food, clothing, shelter, medical care, and reasonable safety-it transgresses the substantive limits on state action set by the Eighth Amendment and the Due Process Clause.[11]

Thus, the State may not divest itself of at least these Constitutional responsibilities by what is uniformly a process whereby parents (and the courts) are provided false information about the psychotropic drugs and parents regularly coerced into giving consent.

In its Motion for Judgment on the Pleadings the State goes on to state:

> Insofar as plaintiff disagrees with the practice of pediatric psychiatry and the culture of pharmaceutical marketing and prescribing practices related to psychotropic medication, those matters are not within the Department's meaningful control.[12]

Here, the State admits court intervention is required to protect the children and youth of whom it has taken custody. If the State is incapable of protecting the children and youth in its custody from harmful psychiatric drugging, this Court must step in and do so. It is their right. Of course, this depends on PsychRights proving the current "culture of pharmaceutical marketing" and pediatric psychopharmacology is indeed harming the children and youth of whom the state has seized custody. PsychRights is refraining from loading up this opposition to the State's Motion to Stay Discovery with the piles of evidence on this, but has no doubt it will establish this. In fact, the State does not truly dispute this[13] and PsychRights is not seeking discovery from the State on this issue.

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[11] *DeShaney v. Winnebago County Department of Social Services*, 489 U.S. 189, 200, 109 S.Ct. 998, 1005 (1989).

[12] Motion for Judgment on the Pleadings, page 20.

[13] In its Answer, the state responds that it "is without sufficient information to admit or deny the substance" of PsychRights' allegations regarding the lack of scientific support for the bulk of pediatric psychopharmacology, the great harm it causes, and the far better results achieved if non pharmacological approaches. It is the State's responsibility to

However, there are issues raised in the State's Motion for Judgment on the Pleadings for which PsychRights does seek discovery from the State. The first is to rebut the unsupported and untrue assertion made by the State in its Motion for Judgment on the Pleadings that the State has nothing to do with authorizing and administering psychotropic drugs to children and youth whom it has taken away from their parent(s).[14] The second is to supply the lack of specificity regarding the State's inappropriate payment for and administration of psychotropic drugs to Alaskan children and youth.[15]

III. Discovery Plan

PsychRights has a very focused discovery plan designed to develop evidence in a logical order and minimize the burden on both sides.[16] The first step is to obtain information on the State's computerized records to enable PsychRights to fashion a focused discovery request to extract relevant information. The second step is to obtain evidence regarding how pediatric psychopharmacology is actually practiced on Alaskan children and youth in State custody and through Medicaid. This involves information from both the State and other parties, such as psychiatrists. In addition PsychRights intends to seek negative data about the drugs that have heretofore been hidden by pharmaceutical

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know. Moreover, PsychRights specifically provided the scientific analysis, including references even prior to bringing suit. *See*, Exhibit G. to Amended Complaint.

[14] Motion for Judgment on the Pleadings, p. 5 ("In short, the administration of psychotropic medication to children in Alaska is a decision left to the parent or legal guardian of the child, or to the superior court.").

[15] Motion for Judgment on the Pleadings, pp 8-9, 18.

[16] For example, PsychRights was originally going to notice a Civil Rule 30(b)(6) deposition covering a large number of topics, but has been working to refine its discovery so as to minimize the burden on all concerned.

companies as well as the improper promotion of pediatric psychopharmacology by pharmaceutical companies.

IV. Currently Requested Discovery

Attached hereto as Exhibits A & B, respectively, are the Notice of Deposition for Mr. David Campana and PsychRights' First Requests for Production.[17] The only items sought are (1) information about the State's computerized records so that PsychRights can fashion requests for production informed by knowledge of what data is available and how it is organized, and (2) the records of seven specific individuals who are or have been in the custody of the State and who have authorized and directed the State to provide such information.[18]

A. The David Campana Deposition

> On January 29, 2009, PsychRights e-mailed the State as follows:
>
> Can we meet informally with David Campana in the near future to formulate a request for production of computerized Medicaid records rather than take his deposition. What I'd like to do is meet with him with our computer person to formulate the request for production. I am not asking that you waive any rights to object to a request for production.[19]

The State responded that it would prefer to conduct a formal deposition[20] and the parties agreed to conduct the deposition on February 26, 2009.[21] However, two days before the scheduled deposition, the State e-mailed:

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[17] The First Requests for Production includes identifying information which has been redacted from the copy attached hereto.
[18] *See*, Exhibit B, pages 8-14.
[19] Exhibit C, page 2.
[20] Exhibit C, page 1.
[21] *See*, Exhibit D.

> In preparing for Dave Campana's upcoming deposition, Stacie and I have taken a more extensive look at the complaint and we have concerns about engaging in discovery at this point. As a result of our review we are preparing a dispositive motion that we hope to file in the next two weeks. Therefore we would request that you agree to postpone Dave's deposition until after the court has ruled on our motion. If you are unable to agree to that postponement, we'll file an expedited motion to quash the deposition on similar grounds. We apologize for the late notice but we need to know by COB today if you can agree to this plan.[22]

PsychRights replied:

> I will agree to postpone it for two weeks or maybe a bit more, but I don't think I can agree to anything that open-ended.[23]

The State responded:

> Good enough Jim, we understand that concern. Thanks for your understanding and courtesy on this point and we will be in touch. Procedurally, will you be issuing a notice that cancels Thursday's deposition?[24]

PsychRights responded:

> I will serve you with a re-notice of deposition for say three weeks out, which when we get closer we will presumably have another discussion about.[25]

The State responded to this as follows:

> That's fine, with the understanding that we're not agreeing to a date certain at this point and re-notice will be subject to further discussions and/or motion practice as we get closer to the time. So I believe we're on the same page with how to proceed.[26]

Instead of further discussion, the State filed the instant Motion to Stay Discovery.

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[22] Exhibit E, page 2.
[23] Exhibit E, page 1.
[24] *Id.*
[25] *Id.*
[26] *Id.*

As mentioned above, the primary purpose of the Campana Deposition is simply to learn about the State's computerized Medicaid records in order to fashion requests for production pertaining thereto. This should be easy for the State to do, especially since it has already assembled this information in connection with *Alaska v. Eli Lilly & Co.*, 3AN 06-05630 CI.[27]

B. First Requests for Production

(1) Descriptions of Computerized Records

Mr. Campana's deposition was noticed under the concept that conducting it would serve as a template for obtaining information about the other relevant computerized records of the State. However, due to the State's delaying the deposition for an extended period of time, PsychRights determined it had to at least get the ball rolling on acquiring the information on all of the State's computer systems relevant to the authorization and administration of psychotropic drugs to children and youth in order to fashion specific requests for production of relevant computerized records. Thus, on March 3, 2009, PsychRights served its First Requests for Production, requesting information on the structure of the computerized records for not only the Medicaid database, but those by the other agencies involved, to wit: the Office of Children's Services, the Division of Juvenile Justice, the Alaska Psychiatric Institute and the Division of Behavioral health. These requests for production asked for the following information:

1. Software utilized,
2. Manuals,
3. File format,

[27] Exhibit F.

4. File structure,
5. The identity and meaning (including codes and/or lookup tables, etc.) of all fields contained in such computerized records, and
6. Examples of all report types.[28]

Again, the purpose of these requests is to enable PsychRights to fashion focused requests for production of relevant computerized records. It is PsychRights' expectation that this will obviate the need for broad requests for production of individual paper case files. However, to the extent PsychRights is left with insufficient time to first obtain the information on the data structure of the computerized records, then obtain the relevant computerized records, and then obtain focused and/or randomly generated case files, it may be forced to serve requests for production of all the case files.

While at first blush it seems there is plenty of time, by all indications the State is going to object every step of the way and time will be used up at each step. If PsychRights is left without sufficient time to go through the steps that will allow it to fashion focused discovery requests, it will be forced to seek broader discovery.

(2) Seven Specific Case Files

The only other discovery requested to date are the case files of seven Alaskan youth who are or have been in State custody and who have, to the extent of their authority, authorized and directed the State to provide PsychRights with the requested information.[29]

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[28] Exhibit B, pages 4-6.

[29] *See,* Exhibit B, pages 7-14. Again, the identifying information has been redacted because it does not appear there is any reason why it should be included in this public filing and it is not believed the identity of the specific persons involved is relevant to the Court's consideration.

If the State has objections to providing these records, it should make such objections known now so they can be considered in an orderly manner.

V. Contemplated Discovery

A. Psychiatrists, the Public and the State Have Been Duped Into Giving Children and Youth Ineffective and Dangerous Drugs

One of the key questions in this case is why psychiatrists are prescribing and custodians are authorizing the administration of extremely improvident and harmful psychiatric drugs to children and youth. The answer is that the pharmaceutical companies have been very effectively illegally promoting their use, especially the neuroleptics, such as Risperdal, Seroquel, Zyprexa, Abilify and Geodon.

Grace E. Jackson, MD, who has been qualified as an expert witness in a number of PsychRights' adult forced psychiatric drugging cases,[30] testified in May of 2008, about how psychiatrists are being misled by the drug companies into improvident prescribing.

> So essentially what happened in the 1990s is that the journals, more than ever before in history, became a tool of marketing, a marketing arm for the drug companies. And drug companies shifted in terms of previous research in the United States.
>
> Most of the research had previously been funded by the government and conducted in academic centers. In the 1990s, that was pretty much over, and most of the funding is now coming from the pharmaceutical industry. So that's really in a nutshell what happened in the 1990s when I was training.
>
> Now, where are we now? What that means is that the journals that most doctors are relying upon for their continuing information continued to be dominated by pharmaceutical industry funded studies and by papers which

[30] *See*, e.g., Exhibit L, page 3 (Transcript page 111, lines 12-18).

> are being written, if not entirely by the drug companies, then by authors who have part of their finances paid for by the drug companies.[31]

In a 2007 article, Pediatric Bipolar Disorder: An Object Study in the Creation of an Illness,[32] the Scottish psychopharmacology expert, David Healy, MD, describes, among other things, how academics have become marketing arms of the pharmaceutical companies instead of objective researchers. This has recently been further buttressed through documents obtained in discovery and recently made public from various lawsuits.

(1) Risperdal/Joseph Biederman, MD/Harvard's Mass General Hospital and the Johnson & Johnson Cetner for Pediatric Psychopathology

On November 25, 2008, the New York Times ran a story titled, Research Center Tied to Drug Company,[33] about Joseph Biederman, MD, and his undisclosed payments by Johnson & Johnson to produce "academic" research in support of prescribing Risperdal to children and youth as young as four.[34] The article describes the vast influence Dr. Biederman has had in the explosion of prescribing the dangerous neuroleptics,[35]

> Dr. Biederman's work helped to fuel a 40-fold increase from 1994 to 2003 in the diagnosis of pediatric bipolar disorder and a rapid rise in the use of powerful, risky and expensive antipsychotic medicines in children. Although many of his studies are small and often financed by drug makers, Dr. Biederman has had a vast influence on the field largely because of his position at one of the most prestigious medical institutions in the world.

In his recent deposition Dr. Biederman testified as follows:

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[31] Exhibit L, page 5 (Transcript page 119).
[32] Exhibit H.
[33] Exhibit I.
[34] Exhibit K, p.2, 4.
[35] This class of drugs is also often referred to by the misnomer, "antipsychotic." *See*, e.g., *Sutherland v. Estate of Ritter*, 959 So. 2d 1004, 1006 n.3 (Miss. 2007)

Q. And do you agree that you are one of the most forceful advocates of the aggressive [psychiatric drug] treatment of preschoolers? . . .

A. I am.[36]

Later in his deposition, Dr. Biederman admitted that he promoted the use of Risperdal in children as young as pre-schoolers (ages four to six[37]), even though no one knows what Risperdal does to the brain and there are no long term studies.[38]

One of the recently unsealed documents includes an e-mail exchange about the Johnson & Johnson Center for Pediatric Psychopathology (J&J Center), in which Dr. Biederman, the Center's leader is recognized as "the pioneer in the area of [Child & Adolescent] Bipolar Disorders,"[39] and that

> He approached Janssen multiple times to propose the creation of a Janssen-MGH center for [Child & Adolescent] Bipolar disorders. The rationale of this center is to generate and disseminate data supporting the use of risperidone in this patient population.[40]

Johnson & Johnson funded the center and the 2002 Annual Report states:

> The mission of the Center is to create a common ground for a strategic collaboration between Johnson & Johnson (J&J) and the Pediatric Psychopharmacology Research Program an[d] at the Massachusetts General Hospital (MGH). . . . An essential feature of the Center is . . . it will move forward the commercial goals of J&J. . . .
>
> Equally important . . . is the demonstration of the validity of [child psychiatric] disorders. . . . Without such data, many clinicians question the wisdom of aggressively treating children with medication, especially those

[36] Exhibit K, p. 4 from February 27, 2009, deposition transcript of Joseph Biederman
[37] Exhibit K, p. 2.
[38] Exhibit K, p. 5.
[39] In his deposition, Dr. Biederman agreed that he was one of the leaders and that he is considered a "world-renowned child psychiatrist." Exhibit K, p. 3.
[40] Exhibit J, emphasis added.

> like the neuroleptics, which expose children to potentially serious adverse events.". . .
>
> We will generate and publish data on the efficacy and safety of medications for . . . child psychopathology. This work is an essential precursor to the . . . widespread use of medications given that most must be used off-label.. . .
>
> Many children with psychopathology never receive medical treatment due to controversies in the media and debates among professionals about the validity of psychiatric diagnoses in children.[41] . . .
>
> To have an impact on clinical practice, research results from the Center must be disseminated through scientific publications, presentations and national and international meetings and continuing education programs. Our program of dissemination is as follows: . . .[42]
>
> In 2002, we made progress in the following areas: . . .
>
> - We disseminated the results of our work [at] national and international meetings.
> - We prepared initial manuscripts for publication. . . .
> - We developed and maintained a schedule of regular communication with J&J staff to facilitate collaborative efforts.
> - We initiated Yearly Meetings of Experts in Bipolar Disorder[43]
>
> To address the controversy about pediatric bipolar disorder, we initiated a multi-year conference series which seeks to establish a forum for researchers and clinicians to improve dialogue and foster collaborative studies about children who present with extreme temper tantrums and dysregulated mood.[44]

Then Dr. Biederman states that the Center's plans for the future include establishing the efficacy of Risperdal for (the controversial diagnosis of[45]) pediatric Bipolar Disorder (BPD) and Obsessive Compulsive Disorder (OCD).[46]

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[41] Exhibit S, p. 3-4, emphasis added.
[42] Exhibit S, p. 6.
[43] Exhibit S, p. 7.
[44] Exhbit S, p. 16.
[45] *See*, Exhibit S, p. 4.

The 2003 Business Plan for the J&J Center shows Dr. Biederman's plans to use the J&J Center as a front to (1) "re-analyze" the safety database,[47] and (2) deal with the problem that Risperdal is not approved for any indication for pediatric use.[48] The 2003 Business Plan presentation also discusses the opportunities for partnerships with advocacy groups, which means funding of groups such as the National Alliance for the Mentally Ill to promote its use in children and youth.[49]

These documents show in more detail what Dr. Jackson testified to, and Dr. Healy wrote about, as set forth above, how "Key Opinion Leaders" are being paid handsomely to prostitute their academic positions to promote the commercial interests of their drug company sponsors.

Dr. Biederman's egregious conduct in this regard recently prompted United States Senator Grassly, just a few days ago, on March 20, 2009, to write to the presidents of Harvard University and Massachusetts General Hospital (MGH), which house the J&J Center, about their organizations being used to produce and disseminate what appears to be fraudulent information in support of prescribing Risperdal to children and youth.[50]

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[46] Exhibit S, page 18.
[47] Exhibit T, page 3
[48] Exhibit T, page 4, 5.
[49] Exhibit T, page 3, 4. Dr. Healy also mentions these parent pressure groups in his article about the creation of pediatric bipolar disorder. Exhibit H, p. 1
[50] Exhibit M.

(2) Eli Lilly and Zyprexa

Eli Lilly & Co (Lilly) recently plead guilty to the illegal marketing of Zyprexa to the elderly and agreed to pay $1.4 Billion in criminal and civil fines.[51] While Lilly may have been able to negotiate away pleading guilty to the off-label promotion of Zyprexa to children and youth, Dr. Healy noted that Lilly had identified the potential for marketing Zyprexa to the children and youth market as early as 1997.[52]

At the January 17, 2007, hearing in *In Re: Zyprexa Litigation* (*Zyprexa MDL*),[53] the following testimony was presented about the illegal off-label marketing of Zyprexa revealed by previously secret documents:

> [T]he documents document the fact that Eli Lilly knew that the -- that Zyprexa causes diabetes. They knew it from a group of doctors that they hired who told them you have to come clean. That was in 2000. And instead of warning doctors who are widely prescribing the drug, Eli Lilly set about in an aggressive marketing campaign to primary doctors. Little children are being given this drug. Little children are being exposed to horrific diseases that end their lives shorter.[54]

(3) Astra-Zeneca and Seroquel

In Re: Seroquel Products Liability Litigation (*Seroquel MDL*)[55] is a consolidation of many products liability lawsuits against the manufacturer of Seroquel, AstraZeneca, for, among other things, (a) AstraZeneca's concealment of Seroquel's propensity to cause diabetes and other related life threatening and deadly conditions, (b) illegal off-label

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[51] *See*, Exhibit G.
[52] Exhibit H, n 39.
[53] MDL 04-1596, United States District Court for the Eastern District of New York.
[54] Exhibit W, page 3.
[55] Multi-District Litigation (MDL) Case #: 6:06-md-01769-ACC-DAB, United States District Court, Middle District of Florida

marketing, and (c) violation of state consumer protection laws, including AS 40.50.471, *et seq*.[56]

As is apparently typical in these cases,[57] a global protective order was entered under which over 30 million pages of material was produced in discovery,[58] with various mechanisms for their becoming unsealed.[59] On December 12, 2008, the plaintiffs challenged the confidentiality designation of over 60 of these documents, which under §12 of the protective order caused them to automatically lose confidentiality protection unless AstraZeneca filed a motion to maintain confidentiality within 30 days.[60] AstraZeneca filed such a motion on January 12, 2009,[61] and a hearing on the motion set for February 26, 2008.[62]

On February 9, 2009, PsychRights e-mailed the lead plaintiffs' attorney, Camp Bailey, indicating it anticipated having a subpoena issued to take Mr. Bailey's deposition and obtain (a) certain specified documents, (b) information on other negative effects, (c) unpublished studies, including those involving children and youth, and (d) documents

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[56] Master Complaint, Docket No. 42. ¶86(a) is the allegation regarding the Alaska consumer protection violation count, which, along with the rest of the public docket in the *Seroquel MDL* case is available on PACER, the United States Court System's electronic access system, and of which this Court can take public notice.
[57] Without comparing them word for word, the protective order in the *Seroquel MDL* appears to be substantially identical to the one in the *Zyprexa MDL*.
[58] *In Re: Seroquel MDL*, Docket No. 1222, p. 5.
[59] *In Re: Seroquel MDL*, Docket No. 478.
[60] *In Re: Seroquel MDL*, Docket No. 478.
[61] *In Re: Seroquel MDL*, Docket No. 1222.
[62] *See*, Exhibit R, page 1.

regarding the promotion of Seroquel for pediatric use.[63] Under ¶14 of the protective order, upon being served with such a subpoena Mr. Bailey is required to notify AstraZeneca, cooperate with AztraZeneca, and give them a reasonable opportunity to object, prior to producing the documents.[64]

The parties agreed to the release of many of the documents before the February 26, 2009, hearing and on February 27, 2009, a number of documents were unsealed, including a July, 2008, Clinical Overview on Weight Gain in Pediatric Patients on Seroquel.[65] It seems as a result of this study, on December 18, 2008, in a letter that was also unsealed on February 27, 2009, the Food and Drug Administration directed AstraZeneca to advise doctors through the labeling that the safety and effectiveness of Seroquel has not been established for pediatric patients and is not approved for patients under the age of 18 years.[66] As far as PsychRights has been able to determine, at this point, this warning has yet to be conveyed to doctors through the directed changes to the label.

The unsealed documents include e-mails regarding AstraZeneca's suppression of unfavorable studies while promoting favorable data:

> There has been a precedent set regarding "cherry picking" of data. This would be the recent Velligan presentations of cognitive function data from Trial 15 (one of the buried trials). Thus far, I am not aware of any repercussions regarding interest in the unreported data.
>
> That does not mean that we should continue to advocate this practice. There is growing pressure from outside the industry to provide access to all data

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[63] Exhibit R.
[64] *In Re: Seroquel MDL*, Docket No. 478.
[65] Exhibit O.
[66] Exhibit N, page 2.

> resulting from clinical trials conducted by industry. Thus far, we have buried Trials 15, 31, 56, and are now considering COSTAR.
>
> The larger issue is how do we face the outside world when they begin to criticize us for suppressing data.[67]

On March 18, 2009, the Washington Post reported as follows about "Study 15:"

> The results of Study 15 were never published or shared with doctors, even as less rigorous studies that came up with positive results for Seroquel were published and used in marketing campaigns aimed at physicians and in television ads aimed at consumers. The results of Study 15 were provided only to the Food and Drug Administration -- and the agency has strenuously maintained that it does not have the authority to place such studies in the public domain. . . .
>
> The saga of Study 15 has become a case study in how drug companies can control the publicly available research about their products, along with other practices that recently have prompted hand-wringing at universities and scientific journals, remonstrations by medical groups about conflicts of interest, and threats of exposure by trial lawyers and congressional watchdogs.[68]

It appears Study 15 may have been unsealed on March 13, 2009, and PsychRights is attempting to get it reviewed. However, it also appears with other documents of interest to PsychRights produced in the *In Re: Seroquel MDL* are still being kept secret, including (1) Study 144, Study 125 and its draft manuscript, Study 165, Study 127, (2) the Investigational New Drug Application (IND) to the FDA, and (3) marketing call notes.[69]

B. The Necessity of Determining the Bases Upon Which Current Pediatric Psychopharmacology is Practiced.

It is necessary for PsychRights to be able to depose at least a few child psychiatrists, and perhaps other physicians and other people prescribing psychotropic drugs to Alaskan

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[67] *See*, Exhibit P, p. 2. That Trial 15 is still buried is revealed
[68] Exhibit Q.
[69] Exhibit R, pages 4 & 5.

children and youth, to have them disclose upon what they are relying in doing so. In addition, since it is illegal for the State to use Medicaid to pay for medications unless they are prescribed for FDA approved indications or included in three specified compendia,[70] and nearly all prescriptions of psychotropic medications to children and youth are off label,[71] it is essential that these prescribers identify where in such compendia such prescribing is included. It is expected that, especially with respect to the neuroleptics and the anti-seizure medications re-branded as "mood stabilizers," they are prescribing these drugs based on off-label marketing by the pharmaceutical companies masquerading as science. Even with respect to the stimulants, such as Ritalin, which have been approved for children and youth, the truth is there is a lack of data supporting long-term efficacy or safety,[72] and it is necessary for PsychRights to learn upon what these prescribers are relying for these drugs as well in order to demonstrate to this Court such prescribing practices are not in Alaskan children and youth's best interests.

Starting in mid-February, PsychRights started trying to coordinate deposition schedules for some psychiatrists with the State's schedule, wanting to give everyone at

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[70] *Ex Rel Franklin v Parke Davis,* 147 F.Supp.2d 39 (DMass2001).
[71] Exhibit S, page 3 ("[N]early all psychiatric medication use in children is off label").
[72] *See*, ¶s 154, 156-165 of the Amended Complaint herein; APA Working Group on Psychoactive Medications for Children and Adolescents. (2006); and Report of the Working Group on Psychoactive Medications for Children and Adolescents. Psychopharmacological, psychosocial, and combined interventions for childhood disorders: Evidence-base, contextual factors, and future directions, Washington, DC: American Psychological Association; National Institute of Mental Health Multimodal Treatment Study of ADHD Follow-up: 24-Month Outcomes of Treatment Strategies for Attention-Deficit/Hyperactivity Disorder, MTA Cooperative Group, *American Academy of Pediatrics*, 113;754-761 (2004)

least a month to prepare.[73] To the extent discovery is stayed for any length of time, the luxury of being able to give the psychiatrists so much notice and accommodate the State's schedule will be diminished.

Most importantly, it is anticipated that this discovery will result in grounds for one or more preliminary injunctions because of the extreme harm being inflicted on Alaskan children and youth by these practices. No further delay should be countenanced. It is also anticipated that this discovery will result in grounds for at least a partial summary judgment for declaratory relief.[74]

C. The Necessity of Developing the True Involvement of the State.

In its Motion for Judgment on the Pleadings the State asserts the administration of psychiatric drugs to children and youth in its custody "is left to the parent or legal guardian of the child, or to the superior court."[75] This is disingenuous at best[76] and PsychRights intends to conduct focused discovery to show the State's true involvement. It is PsychRights understanding, the "consents" are virtually always obtained because one or

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[73] Exhibit D, p.1.

[74] The State has essentially admitted it is not protecting the children and youth in its care and this discovery will provide the detail for the declaratory judgment aspect. The more difficult task will be to fashion the injunctive relief if the State continues to be unwilling to voluntarily take the appropriate steps. It is PsychRights hope that if such preliminary relief is obtained, the State and PsychRights will be able to fashion a program that will only authorize the administration of psychotropic medications to Alaskan children and youth in state custody or through Medicaid in appropriate circumstances and under appropriate conditions.

[75] Motion for Judgment on the Pleadings, p. 5.

[76] It is also patently untrue because under AS 47.10.084, if parental rights have been terminated and there is no guardian, which is often the case, these residual parental rights accrue to the State.

more of the defendants seek such consent (or court order) and that parents are often subjected to extreme pressure to agree to the psychiatric drugging of their children. Thus, another aspect of PsychRights' discovery plan is to have the defendants disclose the sources and information it is

(a) relying upon in deciding to seek, and

(b) providing in obtaining,

parental consent and court orders.

Assuming PsychRights obtains the computerized records it intends to seek, PsychRights is contemplating generating a random sample of case files for review to get an objective view of the actual process. Because of the expectation that the State will interpose every objection it can to each and every one of PsychRights' discovery requests, there is likely to be a series of motions related thereto, which will be the occasion for further delay which could seriously jeopardize the entire discovery plan.

For example, even with respect to obtaining information about the file structures of the State's computerized records in order to be able to fashion a discovery request to obtain the actual computerized records, the State first refused to informally provide the information, then it agreed to a deposition date, and then at the last minute it moved for the instant stay. This has been going on since January.[77]

As set forth above, there is an extant request for production of seven case files, <u>for which authorizations have been given</u> and, based on the State's past behavior one can

[77] *See*, Exhibit C., page 2.

expect it will even object to providing that information, necessitating a motion to compel. For example, on January 20, 2009, the State raised the issue of state confidentiality laws in connection with getting a qualified protective order in place under federal law and PsychRights asked it to identify such laws.[78] The State has thus far failed to do so, but can be expected to interpose it when it has to do so. Presumably the State will do so in response to PsychRights First Requests for Production, served March 3, 2009, and this should not be further delayed.

Just as discovery of what prescribers are relying upon in giving psychotropic drugs to Alaskan children and youth is likely to generate evidence for one or more preliminary injunctions and partial summary judgments, the discovery sought from the State is likely to do the same. Stopping Alaskan children and youth from being subjected to these improvidently administered and harmful drugs should not be delayed through a stay of discovery.

In addition, as set forth above, in *Chavous*, which the State cited, the court held a trial court ordinarily should not stay discovery which is necessary to gather facts in order to defend against a motion to dismiss and that discovery should precede consideration of dispositive motions when the facts sought to be discovered are relevant to consideration of the particular motion at hand. In its Motion for Judgment on the Pleadings the State asserts it plays no role in the psychiatric drugging of children and youth in its custody and through Medicaid. The State bringing this issue into the Motion for Judgment on the

[78] Exhibit U.

Pleadings, even though it was not supported by any competent evidence, means PsychRights must be allowed to conduct discovery on the issue before this Court may properly consider it.

D. The Necessity of Obtaining Pharmaceutical Company Off-Label Marketing Information

In addition to deposing some psychiatrists and other prescribers regarding the off-label marketing to which they have been subjected by the drug companies, PsychRights intends to seek such materials directly from the pharmaceutical companies and/or from parties having access to discovery depositories concerning these matters. It seems likely that the pharmaceutical companies will object and to the extent that deponents can not be served in Alaska, a commission/letter rogatory for an out of state subpoena must be obtained pursuant to Civil Rule 28(b) and then procedures pursued in another state to have a subpoena issued and enforced. This very well might consume a considerable amount of time -- even to the point of still being unresolved as of the date trial is scheduled. There is no reason for such delay. It certainly isn't a burden on the State, which is the basis for its Motion for Stay. This information is very important to acquire for the Court to get the whole picture about what is transpiring with respect to the administration of psychotropic drugs to Alaskan children and youth.

E. The Necessity of Acquiring Suppressed Data

PsychRights believes it can demonstrate, based on publicly available information, that the current practice of psychopharmacology is ineffective and counterproductive, is doing great harm, and non-pharmacological psychosocial approaches should be used

instead in most cases,[79] but to the extent this Court might find this insufficient, PsychRights is entitled to seek suppressed studies and evidence related to the off-label marketing of psychotropic drugs for pediatric use. Moreover, this information could be very important in fashioning the form of the injunction sought herein. It is likely the pharmaceutical companies will object to this discovery, and whether or not the discovery should be had, and if so, to what extent this information should be kept secret by this Court, will take some time. As with the evidence sought from the drug companies with respect to the off-label marketing to Alaskan prescribers, this very well might consume a considerable amount of time -- even to the point of still being unresolved as of the date trial is scheduled. There is no reason for such delay with its concomitant extreme harm to the children and youth of Alaska in State custody, nor the disadvantaged children and youth of Alaska who are being subjected to these drugs through Medicaid payments.

VI. Overview

Psychiatrists ought to be able to rely on the information they receive through medical journals and continuing medical education.[80] The State ought to be able to trust that psychiatrists recommending the administration of psychiatric drugs are basing these recommendations on reliable information. Unfortunately, neither of these things which ought to be true are true. It is essential for PsychRights to establish the extent of the administration of psychiatric drugs to Alaskan children and youth in State custody and

[79] *See*, e.g., the CriticalThinkRx Curriculum, including references, that can be accessed from http://criticalthinkrx.org/.
[80] They should be skeptical, however, about "information" provided by drug companies.

through Medicaid. It is essential that PsychRights establish upon what the psychiatrists are relying in prescribing psychiatric drugs to Alaskan children and youth in State custody and through Medicaid in order for this Court to determine whether current practice sufficiently protects Alaska's children and youth in state custody and whether or not Medicaid is making illegal payments for psychiatric medication to Alaskan children and youth.

The trial in this case is set to begin on February 1, 2010. At first blush, this seems a fair way off, but pretrial deadlines are now looming. The deadline for preliminary witness lists and identification of retained experts is August 31, 2008, just five months from now. The other deadlines follow-on quickly. These deadlines are simply coming up too fast for any delay of any length.

Moreover, by inserting into its Motion for Judgment on the Pleadings, however improperly, that the State plays no role in the authorization of these drugs to children and youth of whom the State has seized custody, the State has set up the situation where discovery with respect to this situation may be necessary in order to determine the motion.[81] Thus, discovery must be allowed to proceed without further delay.

PsychRights has a very focused discovery plan designed to produce the necessary evidence. This discovery plan depends on the discovery occurring in a certain order and to the extent that discovery is delayed for any length of time, the ability to conduct the discovery with minimal burden on the parties is jeopardized.

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[81] PsychRights believes the Motion for Judgment on the Pleadings is so devoid of merit that this Court should have no difficulty in denying it without consideration of the unsupported assertions of the State that it plays no role in the administration of psychiatric drugs to children and youth in State custody.

Most importantly, Alaskan children and youth are being greatly harmed by the State's admitted inability to properly care for and protect them from the improvident, psychiatric drugging and this should cease as soon as possible. Discovery should not be further delayed and prevent this.

VII. CONCLUSION

For the foregoing reasons, PsychRights respectfully urges this Court to deny the State's Motion to Stay Discovery

DATED: March 24, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein, ABA # 7811100