CIRCUIT COURT FOR THE STATE OF MICHIGAN
INGHAM COUNTY CIRCUIT COURT
THIRTIETH JUDICIAL DISTRICT

BEN HANSEN,

Plaintiff

v, **Case No. 06-1033 CZ**

STATE OF MICHIGAN, DEPARTMENT OF COMMUNITY HEALTH

Defendant. **Judge Beverley Nettles-Nickerson**

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SUPPLEMENTAL BRIEF IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

INTRODUCTION

FACTUAL BACKGROUND

This Supplemental Brief is being filed with the understanding of the parties and this Court's Order for Private Review of Records, entered on November 6, 2006. To help reorient the Court as to the status of this matter a brief background statement is being provided, along with the relevant current factual background.

On August 30, 2006, Plaintiff, a sitting member of the Michigan Department of Community Health Recipient Rights Advisory Committee, filed a Complaint seeking to compel the Michigan Department of Community Health (MDCH) to make available documents, statements, etc., pursuant to the Michigan Freedom of Information Act. M.C.L. § 15.231, et.seq; M.S.A. § 4.1801 (i), et seq. The information, data and documents being sought, which were not provided pursuant to a number of freedom of information requests, pertain to a 2004 MDCH program entitled the Pharmacy Quality

Improvement Project (PQIP).

PQIP stated purposes include improving the "effectiveness" of the taxpayer's dollars spent on psychotropic drugs, "patient adherence to medication plans" and the "quality of psychotropic prescribing practices based on evidence based guidelines." To help run PQIP, a three-way agreement between MDCH, Comprehensive Neuroscience (CNS) and Eli Lilly and Company was entered into. CNS received a grant from Eli Lilly and Company. It's role was and is to receive, sort and analyze data. Eli Lilly was to "provide certain funding." (There is no mention in the available documents of Eli Lilly having the right to participate in any meetings, workshops or discussions with regard to PQIP or the data collected. The records provided to date, however, reveal an Eli Lilly representative has participated in PQIP meetings and apparently repeatedly viewed data provided by CNS.) Exhibit A.

In response to the Complaint MDCH filed a Motion to Dismiss. The issues were briefed and the parties appeared for oral argument on November 1, 2006. At that time, an interim agreement was reached by the parties, as reflected in the November 6, 2006 Order for Private Review of Records.

As of this writing, considerable documents have been provided by MDCH. Such were provided pursuant to the above referenced Order and subsequently filed Freedom of Information Act Requests. Information and documents provided to date include:

1. Michigan Behavioral Pharmacy Reports;
2. Michigan Concurrent Drug Reports;
3. BPMS Mailing Summary Reports & PQIP Mailing Logs;
4. Michigan Physician Specialty and Response Reports;
5. Michigan Targeted Prescriber Change Reports;
6. PQIP Impact Analysis;
7. PQIP Summary Trend Charts;
8. Michigan Managed Care & Michigan Fee-for-Service Pharmacy Reports;

9. Michigan Targeted Patient Change Reports;
10. Executive Management Reports.

To be able to evaluate these reports and what has not been provided and the disagreement between the parties, it is necessary to review a couple of examples. For example, there is the Michigan Behavioral Pharmacy Report for Children Under 5 for January 1, 2005-August 31, 2005. Exhibit B. This report provides some detail of the psychiatric/psychotropic drugs being administered to children under 5 years of age, through State funded programs including:

1. The class of drugs prescribed;

2. The number of patients for each class. (Three thousand sixty-four (3,064) children under 5 were administered some form of psychiatric drug during this three month period at a cost of $467,343.00);[1]

3. The number of prescribers for each class;

4. The number of claims for each class; and,

5. How much state money was spent for each class of drug.

Reports were provided for children under 5 for and for "all ages" for other times as well. (Although, as of this writing, while reports were provided for all ages for time periods in 2006 none were provided for children under 5 for 2006.)

Another example is entitled "Michigan Concurrent Drug Use Report (For All Ages)," for the

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[1] The listed side effects for these drugs is extensive. Two examples include,"anticonvulsants/mood stabilizers" - given to 875 children - side effects include but are not limited to liver damage, pancreatitis, anemia, psychosis, congenital neural tube defects, headaches, nausea and many more. http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.. Certain of these drugs given for "any sympathometric stimulants (given to 391 children) are listed by the Drug Enforcement Administration as Schedule II Controlled Substances which have effects "similar to cocaine." www.usdoj.gov/dea/pubs/abuse/5-STIM.htm. http://www.deadiversion.usdoj.gov/drugs_concern/methylphenidate.htm

period of October 1, 2005 through December 31, 2005. Here, the number of patients taking anywhere from 1 to 16 psychiatric/psychotropic drugs was reported. Exhibit C. During this period an excess of 75,000 people were taking more than one psychiatric drug; more than 21,000 took three (3); close to 9,000 to four (4); and, more than 3,000 took five (5). No details on the drug names or the manufacturers were provided. Such reports were also provided for children under 18 for various other time periods, including a second "Concurrent Drug Use Report" for October 2005 thru December 2005. (While there are two reports with the same dates, they are different as the numbers do not match.)

What was not provided and what is the focus of the disagreement is that the MDCH is refusing to provide:

1. Michigan Under 5 Detail by Drugs and Quality Indicator

2. Patients on 5 or More Concurrent Behavioral Drugs.

Essentially, what this means is that the names of the drugs are not being provided, which would in turn allow the manufacturers to be ~~provided~~ identified. (Why MDCH is willing to provide the above information and not this data is not clear as will be discussed.)

Before closing on this background statement, it will be helpful and of interest to place this dispute in a more complete context. The relevance of this will become clear during the legal argument.

THE BROADER VIEW

Eli Lilly, which funds the research and data collection undertaken by Comprehensive Neuroscience and is participating in the PQIP program, has been the subject of multiple lawsuits with regard to its marketing practices. Recently, for example, the State of Pennsylvania filed suit

against Lilly, Astra Zeneca Pharmaceuticals and Johnson and Johnson, claiming they fraudently marketed antipsychotic drugs and owe the state for prescription costs and harm to patients. The State charged Lilly withheld the risks and exaggerated the benefits of the antipsychotic medication ZYPREXA while persuading doctors to prescribe it for unapproved uses. It is reported that this is the fifth claim of state medicaid program against Lilly. Commonwealth v. Elli Lilly Co., Case No. 00-2836, Feb. Term 2007, Court of Common Please, Philadelphia County, P.A.

The "off-label" use of psychiatric and psychotropic drugs on children and infants is, to say the least, controversial. In a series of articles on the use of "off-label" drugs detail about this and an example of what is taking place in Texas is reported:

> States are beginning to come down on doctors for the off-label prescribing bills submitted to Medicaid. In August 16, 2006, the Houston Chronicle reported that 5 Texas doctors who treat children covered by Medicaid were instructed to return $11,034.43 to the state that was paid out for psychiatric drugs they prescribed.
>
> Two years ago, state officials did a two-month review of Medicaid payments for psychiatric drugs prescribed to Texas children and found that 63,118 children were on stimulants, SSRIs, or antipsychotics, with nearly one-third taking drugs from more than one of those classes. During that 2 month period, review identified 114, 315 claims worth more than $17 million just for kids alone, according to the Chronicle.
>
> Texas has since established strict guidelines as far as prescribing psychiatric drugs to children and doctors have been warned of the consequences of off-label over-prescribing. See, Biggest Off-Label Drug Marketing Scheme in History - Part II, Evelyn Pringle, Freelance Writer. December 1, 2006.

It is, moreover, being reported that in Florida more than 37,000 children (newborns to age 18) were prescribed, in 2005, "off-label" psychotropic drugs (not tested or approved for children), some of which carry "black box" warnings issued by the Food and Drug Administration (FDA).[2] (The FDA in 2004 issued a Public Health Advisory to warn the public about the increased risk of

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[2] See Citizens Commission on Human Rights Florida Press Release, dated September 26, 2006.

suicidal thoughts and behavior in children and adolescents being treated with antidepressant medications.) Plaintiff is not making any accusations but is simply pointing out his concerns and what is occurring elsewhere.

HOW THE INFORMATION CAN BE USED

With this background, it is now possible to take a look at what may be done with this data if it were to be released. The answers, at least in part, come from researchers and professionals in the field. First is Dr. Bertram A. Karon, a PhD, Professor of Clinical Psychology at Michigan State University. He is the former President of the Division of Psychoanalysis of the American Psychological Association and the Michigan Psychoanalytical Council and a Diplomat and Fellow of other professional associates as detailed in his attached CV. Dr. Karon expressed his support for the release of information because:

1. The information will have a useful educational value to researchers as researchers wish to study the changing prescribing patterns of psychiatric drugs to young children in Michigan Medicaid systems;

2. The information will have a useful education value to researchers with regard to the changing prescribing patterns of psychiatric cocktails to patients of all ages;

3. That having the information will assist in maintaining the appropriate standards of the health care profession. Exhibit D.

Next, and in the same vein, is the letter of support from Linda J. Morrison, PhD, MSW, which provides in relevant part:

> As a sociologist and social worker who studies the field of mental health and illness, particularly the experience of psychiatric consumers in the mental health system, I am acutely aware of the importance of access to current data regarding psychiatric treatment. These data will provide vital information regarding the prescribing of psychiatric drugs to children and adults, as well as the cost to our Medicaid system and our taxpayers. As long as the confidentiality of individual patients is protected, such data will enhance our ability to understand current prescribing practices, their

potential for helping and/or harming the vulnerable populations to whom they are prescribed (or overprescribed), and also to understand the trends of these treatment practices and their costs to the taxpayers of Michigan.

This letter and her C.V. are attached. Exhibit E.

ADDITIONAL MATTERS OF CONCERN AND INTEREST

If you Court will bear with us for another few moments there are additional points to consider which also demonstrate the need for the release of the data. These points arise out of a review of what has been provided.

1. At the end of 2005, PQIP began using new reporting formats with some new drug classes. The old and new reporting systems overlapped in the period October through December 2005. Both reports contain the identical subtitle: "Children Under 18, 10/01/2005 through 12/31/2005," but although these reports are for the same age group (under 18) and the same time period (October through December 2005, the data does not match. For example, under the heading "Drug Class," the first report lists the number of patients on "Any Antidyskinetic" as 2,771. Under the same heading, the second report lists the number patients on "Any Antidyskinetic" as 505 (2,266 fewer patients than the first report). Under the new version, one drug class was dropped, and three new classes were added:

The shifting of drugs into and out of different classes results in what appears to cause a net loss of 3, 943 patient claims: 57,652-4,566 + 2,379 + 2,841 + 12,542 = 70,848 (not 66,895). What explains the apparent discrepancy? What happened to the 3,943 Patient Claims that somehow disappeared? If the drugs are listed by name, it wouldn't matter how PQIP chooses to classify, declassify and/or reclassify the 150 psychiatric drugs that the program monitors; drugs could be counted.

2. The most recent data from January 2006 to October 2006 shows an extraordinary300% increase in the adult ADHD category, "Use an ADHD Non-Stimulant and 1 or More Stimulants for 60 or More Days." If the drugs are listed by name this may be explained.

3. If the drugs are listed by name, it can be determined how many are generic vs. brand name products. This would allow researchers to see how brand name drugs fared compared to the much cheaper generics.

4. It is known that thousands of patients are prescribed 5 or more behavioral drugs concurrently, but unless the drugs are listed by name, there is no way to analyze (and criticize) the various combinations of "drug cocktails" our tax dollars

are paying for. For example, a patient prescribed a dozen generic drugs might cost the taxpayer ~~well over a thousand dollars~~ under a hundred per month, but the same patient prescribed a dozen brand name drugs would cost the taxpayer well over a thousand dollars per month.

One last point in closing is that a comparison of the Behavioral Pharmacy Reports from January 2006 and October 2006 show an enormous increase on the use of the drugs. A comparison of the Behavioral Pharmacy Reports from January 2006 to October 2006 shows:

100% increase in children under 18 on 3 or more mood stabilizers.
100% increase in children age 6-17 on 4 or more psychiatric drugs.
79% increase in adults on 5 or more psychiatric drugs.
67% increase in adults on 3 or more psychiatric drugs.
60% increase in adults on 1+ benzodiazepine and 1+ antidepressant.
47% increase in adults on 2 or more antipsychotics.
45% increase in children under 18 on a benzodiazepine for 60+ days.
45% increase in kids under 18 on 2 or more atypical antipsychotics.
34% increase in multiple prescribers of psych drugs to kids under 18. (Exhibit F)

With all of the above in mind, we turn to the legal argument.

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ARGUMENT

It is Plaintiff's understanding that the legal basis for MDCH's refusal to provide the requested data rests with Public Act 270, 1967, as amended; M.C.A. § 331.531, et seq. Specifically because Plaintiff, Ben Hansen, is not a "review entity" as defined in M.C.A. 331.531 (2), he is thus, not entitled to the sought. For a number of reasons this analysis is erroneous. First it must be kept in mind that no personal information is being sought. No names or addresses or details of any individual are being sought. What is being sought is simply raw data - numbers and drug names.

Mr. Hansen has never argued that he is a "review entity." But this is in any event beside the point. The statute with question contemplates that a "review entity" can release information. It does not speak of information only being released to or considered by "review entities." The

Confidentiality section reads as follows:

> The identity of a person whose condition or treatment has been studied under this act is confidential and a review entity shall remove the person's name and address from the record before the review entity releases or publishes a record of its proceedings, or its reports, findings, and conclusions. Except as otherwise provided in section 2, the record of a proceeding and the reports, findings, and conclusions of a review entity and data collected by or for a review entity under this act are confidential, are not public records, and are not discoverable and shall not be used as evidence in a civil action or administrative proceeding. M.C.L. § 331.533. (emphasis added.)

This provision provides quite clearly that: (1) when information is to be released names and addresses are to be removed (not at issue here); and (2) that the information is to be kept confidential "[e]xcept as otherwise provided in Section 2....". (emphasis added.)

Section 2, M.C.L. § 331.532 (2) provides:

> The release or publication of a record of the proceedings or of the reports, findings, and conclusions of a review entity shall be for 1 or more of the following purposes:
>
> (a) To advance health care research or health care education.
> (b) To maintain the standards of the health care professions.
> (c) To protect the financial integrity of any governmentally funded program.

Here again it is clear that reports, findings etc. of a "review entity" can be released for the purposes set forth. These purposes are clear and are exactly what is contemplated are evidenced by Dr. Karon's affidavit and Dr. Morrison's letter.

Having such information would allow for the tracking of drugs taken by any given patient from one period to the next period (without providing the name of the individuals or in any way invading their privacy), which would allow researchers to see the efficacy (or not) of the drugs being administered, whether individuals were being given more and different drugs or whether the drugs being given allowed for fewer or no drugs being administered as time goes on. Plaintiff would have no objection to the Court's order incorporating a statement of these purposes and the applicable

limitations.

The law in Michigan with regard to construing a statute is well settled.

> If the statute's language is clear and unambiguous, we assume that the Legislature [**660] intended its plain meaning and the statute is enforced as written. n3 *People v Stone*, 463 Mich. 558, 562; 621 N.W. 2d 702 (2001). Stated differently, "a court may read nothing into an unambiguous statute that is not within the manifest intent of the Legislature as derived from the words of the statute itself." *Roberts v Mecosta Co Gen Hosp*, 466 Mich. 57, 63; 642 N.W. 2d 663 (2002). "Only where the statutory language is ambiguous may a court properly go beyond the words of the statute to ascertain legislative intent." *Sun Valley Foods Co v Ward*, 460 Mich. 230, 236; 596 N.W. 2d 119 (1999).

The language in question is quite clear and as long as the materials/data are used for the purposes set forth, there is no reason or basis for not releasing the information. Indeed it has apparently already been provided to or made available to the Eli Lilly representative.

Of course, providing the information would be absolutely consistent with and meeting the purpose of the Freedom of Information Act, which is :

> (2) It is the public policy of this state that all persons, except those persons incarcerated in state or local correctional facilities, are entitled to full and complete information regarding the affairs of government and the official acts of those who represent them as public officials and public employees, consistent with this act. The people shall be informed so that they may fully participate in the democratic process. MCLA § 15.231.

The standard to be applied and the burden with respect to denials is quite clear:

> The Court shall determine the matter de novo and the burden is on the public body to sustain its burden. The Court, on its own motion, may view the public record in controversy in private before reaching a decision. MCLA § 15.240 (4) (emphasis added)

CONCLUSION

Defendant has provided quite a bit of information, data, documents and reports. However,

a line is drawn when it comes to simply providing the names of the drugs. This is, to be straightforward, incomprehensible. What purpose is actually served by not providing the drug names? Certainly not one of confidentiality. Plaintiff and others can have information regarding the class of drugs being used and the number of individuals and children being given these types of drugs, but not the names of the drugs. This is arbitrary. It must not be allowed.

For the above stated reasons and based on the authority provided, the Motion to Dismiss must be denied. At the very least, the data must be turned over to the Court for an in-camera review to be followed by the Court's decision, as provided for in M.C.L.A. § 15.240(4).

Respectfully submitted,

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DATED: March 13, 2007

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Hon. Beverley Nettles-Nickerson

Freedom of Information Act Complaint

AG#2006021202

CERTIFICATE OF SERVICE

Krystle Melquiades, being first duly sworn, deposes and says that on the 13th day of March, 2007, she served *Supplemental Brief in Opposition to Defendant's Motion to Dismiss* and this *Certificate of Service* in the above matter to the following via Express Mail Delivery:

Thomas Quasarano (P27982)
Assistant Attorney General
Attorney for Defendant
P.O. Box 30212
Lansing, MI 48909

Krystle Melquiades
KRYSTLE MELQUIADES

Subscribed and sworn to me this 13th day of March, 2007

Sherri R. DiAngelo
NOTARY PUBLIC

SHERRI R. DIANGELO
NOTARY PUBLIC, STATE OF MI
COUNTY OF MACOMB
MY COMMISSION EXPIRES Dec 09, 2012
ACTING IN COUNTY OF WAYNE