UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE ZYPREXA PRODUCTS LIABILITY LITIGATION	:	04-MD-1596

NOTICE OF MOTION

TO ALL COUNSEL OF RECORD (VIA ELECTRONIC CASE FILING):

PLEASE TAKE NOTICE that, upon the attached papers, enjoined parties Vera Sharav and Alliance for Human Research Protection will move this Court, the Honorable Jack B. Weinstein, Senior United States District Judge, Eastern District of New York, 225 Cadman Plaza East, Brooklyn, NY 11201, on short notice on January 16, 2007 for an Order vacating CMO-3 in part (by providing that the documents forming the subject of the temporary injunction entered by this Court on December 29, 2006 and subsequently extended to January 16, 2007 ("Injunction") are not confidential), or, in the alternative, an Order dissolving the Injunction in part.

Respectfully Submitted,

SHERMAN, SILVERSTEIN, KOHL,
ROSE & PODOLSKY, P.A.

By: _____
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Pennsauken, New Jersey
Monday, January 8, 2007

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE ZYPREXA PRODUCTS LIABILITY LITIGATION	:	04-MD-1596

MEMORANDUM OF LAW IN SUPPORT OF THE MOTION OF VERA SHARAV, ALLIANCE FOR HUMAN RESEARCH PROTECTION, AND DAVID COHEN FOR AN ORDER VACATING CMO-3 IN PART, OR, IN THE ALTERNATIVE, DISSOLVING THE INJUNCTION IN PART

INTRODUCTION

Vera Sharav, the Alliance for Human Research Protection ("AHRP"), and David Cohen, by and through their attorneys, Alan C. Milstein of Sherman, Silverstein, Kohl, Rose & Podolsky, P.A., respectfully submit this memorandum of law in support of their motion for an Order vacating CMO-3 in part (by determining that the documents forming the subject of the temporary injunction entered by this Court on December 29, 2006 ("Injunction") are not confidential), or, in the alternative, dissolving the Injunction in part.

The issue before this Court is the public's right to know information critical to any informed decision to take a particular drug. Pharmaceutical companies have a record of concealing information about the adverse effects of their products and giving the public only that which will further the companies' sales, even at the expense of public health.[1] Litigation against pharmaceutical companies is often the only means of curtailing the marketing and sale of drugs to those for whom the risks outweigh any benefits. Too often, however, drug companies and plaintiffs' lawyers agree to suppress from public view, by way of protective orders, the critical

[1] See e.g., moralgroup.com/NewsItems/Drugs/p3.htm (The Wall Street Journal's article on a lawsuit filed by the State of New York against GlaxoSmithKline for engaging in "repeated and persistent fraud" by concealing information about Paxil); see also query.nytimes.com/gst/fullpage.html?sec=health&res=9506E6DD153FF93AA15753C1A9649C8B63 (The New York Times' article, entitled "Documents Show Effort to Promote Unproven Drug," describing Warner-Lambert's marketing of Neurontin).

information revealed in the litigation process. Such protective orders, like the protective order that was agreed to by the plaintiffs and defendant in this case, do not serve the public good and, thus, do not comport to the purposes for which such orders were contemplated under the Federal Rules of Civil Procedure.

STATEMENT OF FACTS AND PROCEDURAL HISTORY

I.

Ms. Sharav is a public advocate for human rights. Her advocacy efforts have focused on human participants in unethical research experiments, as well as patients victimized by concealed drug hazards. Her work is widely followed; she has testified before a panel of experts at the Office of Human Research Protection, served on the Children's Workgroup of the National Human Research Advisory Committee, given testimony before national policy advisory panels, made presentations before the American Public Health Association, presented a paper on medical ethics before a United States military ethics forum, and spoken in academic forums at the University of Texas and Columbia University. She is the author of articles appearing in Ethical Human Psychology and Psychiatry, Journal of Disability Policy Studies, and American Journal of Bioethics.[2]

Ms. Sharav heads the AHRP, a not-for-profit national network of individuals dedicated to advancing responsible and ethical medical practices, as well as ensuring the human rights, dignity, and welfare of participants in the medical enterprise. The AHRP disseminates, through the Internet, daily e-mails called Infomails. The Infomails provide subscribers with information about medical research ethics and drug safety issues affecting vulnerable populations, such as children, the elderly, and people with cognitive or physical disabilities. The Infomails have a wide following among patient advocacy organizations, members of the scientific community,

[2] See Affidavit of Vera Sharav ("Sharav Aff."), attached as Exhibit "A," ¶¶ 1-4.

public officials, the media, medical journal editors, and lawyers. The AHRP also operates the web site ahrp.org and maintains a blog at ahrp.blogspot.com.[3]

Mr. Cohen is also in the public eye. He is a tenured Full Professor of Social Work at Florida International University in Miami. His research and scholarly efforts have focused on how psychotropic medications such as antipsychotics, antidepressants, and stimulants are studied in clinical trials, approved by regulatory agencies, promoted by their manufacturers, prescribed by physicians, and used and experienced by patients. He is the author or co-author of over fifty peer-reviewed articles in publications such as American Journal of Psychiatry, Ethical Human Sciences and Services, and The Encyclopedia of Psychology, as well as twelve books and monographs on withdrawal effects of psychotropic medications, adverse effects of antipsychotic drugs, medicalization, consumer information and empowerment about psychotropic medication.[4]

II.

On or around December 15, 2006, an attorney named James Gottstein contacted Ms. Sharav, who knew him as the principal of a public interest law firm in Alaska devoted to defending people against forced psychiatric drugging. Mr. Gottstein advised Ms. Sharav that, through the use of a Subpoena, he had come into possession of important documents regarding Zyprexa, a drug manufactured by Eli Lilly and Company ("Lilly") and used for the treatment of schizophrenia and certain bipolar disorders (collectively, "Documents"). Mr. Gottstein then forwarded the Documents to Ms. Sharav.[5] Mr. Cohen received the Documents from Mr. Gottstein, via e-mail, around the same time.[6]

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[3] See Sharav Aff, ¶¶ 4-9.

[4] See Affidavit of David Cohen ("Cohen Aff."), attached as Exhibit "B," ¶¶ 1-5.

[5] See Sharav Aff., ¶¶ 10-15. As this Court is well aware, Mr. Gottstein received the Documents from David Egilman, M.D., M.P.H. According to Lilly, Dr. Egilman provided the Documents to Mr. Gottstein in violation of CMO-3, which prohibited Dr. Egilman from disseminating them to any third party. See Docket Entry 999.

[6] See Sharav Aff., ¶¶ 10-15.

The Documents had been designated as confidential by Lilly pursuant to Case Management Order 3, a Protective Order entered on August 9, 2004 ("CMO-3").[7] CMO-3 gives Lilly the unfettered right to designate documents and things as confidential, as long as Lilly "in good faith believes" that they are confidential.[8] It appears that, in entering CMO-3, this Court did not articulate any reasons why a Protective Order was necessary to seal such documents. Nor did this Court set forth any objective criteria whereby the parties could determine whether a document was truly confidential so as to require protection from disclosure.[9] Seemingly, CMO-3 is simply a form of umbrella protective order, agreed to by consent of the parties, authorizing any party producing information to designate any document or testimony as confidential.

Mr. Cohen has reviewed the Documents and believes, based upon his review of them, "that the Documents constitute invaluable information on how antipsychotic drugs are marketed to prescribing physicians, and that the public must have access to in order to better understand how the risks and likely adverse effects of medications prescribed to them are not always fully disclosed either to regulatory agencies who approve these medications, to physicians who prescribe these medications, or to patients or their families who use them."[10] As Mr. Cohen states in his Affidavit,

> I wish to undertake analysis and dissemination of some information contained in the Documents, in the form of articles and other publications destined for professional or popular audiences, in accordance with the research and scholarly interests I have pursued as a university professor for nearly two decades.
>
> For example, an analysis of court documents available to the public from United States ex rel. David Franklin vs. Pfizer, Inc., and Parke-Davis, Division of Warner-Lambert Company was recently published as an article entitled "Narrative Review: The Promotion of Gapapentin: An Analysis of Internal Industry

[7] See Docket Entry 61 (CMO-3).
[8] See Docket Entry 981.
[9] See Docket Entry 61.
[10] See Cohen Aff., ¶ 13.

> Documents," in Annals of Internal Medicine, 2006, Vol. 145, pages 284-293, by authors Michael A. Steinman, MD, Lisa A. Bero, PhD, Mary-Margret Chren, MD, and C. Seth Landfeld, MD. The authors and accompanying editorial about this article recognize that such documents constitute unique opportunities to understand how drugs are marketed to professionals and to be able to properly distinguish marketing from scientific activities. Being able to make such a distinction has large implications for the protection of public health.[11]

Ms. Sharav also believes, based upon her experience, that the Documents constitute invaluable primary sources to which the public must have access. She believes that Lilly designated the Documents as confidential in bad faith. She wishes to disseminate the original Documents through the use of AHRP's Infomails, AHRP's web site and blog, and other means. In Ms. Sharav's view, it is time for the public to be able to see the Documents in black and white.[12]

III.

Ms. Sharav and Mr. Cohen are not alone in believing that the Documents are important. Late last month, The New York Times, whose reporters also received copies of the Documents from Mr. Gottstein, published five detailed pieces summarizing the contents of the Documents.[13] The first two of those articles appeared on the front page. The Times has a print circulation in excess of 1,000,000 copies per day, and individuals across the world access it on the World Wide Web.[14]

As reported in the Times, the Documents reveal that Lilly encouraged primary care physicians to use Zyprexa in patients who had neither schizophrenia nor bipolar disorder. The Times further reported that the Documents reveal that Lilly concealed two side effects of Zyprexa – significant weight gain and the onset of diabetes – because Lilly knew that disclosing

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[11] See Cohen Aff., ¶¶ 16-17.
[12] See Sharav Aff., ¶¶ 10-15.
[13] See Docket Entries 991-995 (containing print-outs of the articles).
[14] See en.wikipedia.org/wiki/New_York_Times (visited January 4, 2007).

these side effects might hurt existing and future sales of the drug. In addition, the Times reported that the Documents revealed that Lilly provided false data to prescribing doctors in an effort to boost sales.[15] The Times went on to report that these marketing efforts proved to be successful. Despite the extremely limited approved uses of Zyprexa, and despite the fact that Zyprexa should only be prescribed by specialists qualified to diagnose schizophrenia and bipolar disorder, Zyprexa became so widely prescribed by primary care physicians and specialists alike that it generated $4.2 billion in sales for Lilly in 2005.[16]

In this Internet age, the lifespan of news stories has increased exponentially. The current entry on Zyprexa in the online encyclopedia Wikipedia contains the following summary of the Times article:

> According to a New York Times article published on December 17, 2006, Eli Lilly has engaged in a decade-long effort to play down the health risks of Zyprexa, its best-selling medication for schizophrenia, according to hundreds of internal Lilly documents and e-mail messages among top company managers. These health risks include an increased risk for diabetes through Zyprexa's links to obesity and its tendency to raise blood sugar.[17]

On December 22, 2006, PharmedOut, "a new project that educates physicians on how pharmaceutical companies influence prescribing," posted a video featuring Shahram Ahari, a former Zyprexa salesman, on the popular web site YouTube.[18] PharmedOut's web site contains the following description of, and link to, the video:

> PharmedOut, a new project that educates physicians on how pharmaceutical companies influence prescribing, is previewing a timely video about Zyprexa (olanzapine), an antipsychotic drug approved by the FDA to treat schizophrenia and bipolar disorder.

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[15] See Docket Entries 991-995.

[16] See Docket Entries 991-995.

[17] See http://en.wikipedia.org/wiki/Olanzapine (visited January 5, 2007). A Google search using the phrase "Zyprexa documents" revealed nearly 10,000 hits on January 5, 2007.

[18] See youtube.com/watch?v=nj0LZZzrcrs&mode=related&search= (visited January 4, 2007); see also ridgewayng.com (visited January 4, 2007) (containing information on Pharmed Out).

> In this video Shahram Ahari, a former pharmaceutical company representative, tells how he sold the drug. Nearly a decade after its introduction, a drug once hailed as a breakthrough treatment is being assailed for its negative side effects. Antipsychotic drugs are not risk-free, but doctors and patients have long complained that Zyprexa causes obesity and diabetes. This week, the New York Times reported that studies on the frequency of weight gain were underreported by the manufacturer. PharmedOut is an independent physician-run project funded through the Attorney General Consumer and Prescriber Education grant program.[19]

IV.

What followed in the wake of the Times articles and surrounding publicity was not a public apology from Lilly. Nor was it a black box warning on the packaging of Zyprexa alerting physicians to be cautious about prescribing the drug off-label or advising consumers of the potential adverse effects of taking Zyprexa. Rather, it was a request for an injunction enjoining the individuals and entities that had come into possession of the Documents from disseminating them.[20] By consent of the parties, the Court entered an Order for Mandatory Injunction providing that Mr. Gottstein was enjoined from further disseminating the Documents.[21] The next day, Lilly's deputy general counsel made the following statement to the Times:

> Lilly is concerned that this deliberate violation of a court order and the selective disclosure of incomplete information may cause unwarranted concern among patients that could cause them to stop taking their medication without consulting their physician. We are pleased with the seriousness with which the court addressed this

[19] See ridgewayng.com.
[20] See Docket Entry 981.
[21] See Docket Entry 61, ¶ 3.

> matter and look forward to Mr. Gottstein's swift compliance with the order.[22]

On or around December 29, 2006, the Honorable Brian M. Cogan, U.S.D.J. entered the Injunction, which enjoined Ms. Sharav, AHRP, Mr. Cohen and others from disseminating the Documents.[23] These parties were given no notice of the application for the Injunction and no opportunity to be heard.[24] Nor were they given notice or an opportunity to be heard before this Court's January 4, 2007 Order for Temporary Mandatory Injunction, which provided as follows, in pertinent part:

> Upon consent of members of the ... Plaintiffs' Steering Committee ... , Lilly ... , and all interested parties appearing before this Court, it is hereby
>
> ORDERED that the ... Injunction ... entered [on] December 29, 2006 is extended to January 16, 2007, and the following individuals, entities, and organizations ... are hereby enjoined from further disseminating [the Documents]: Vera Sherav [sic], ... the Alliance for Human Research Protection (and www.ahrp.org and www.ahrp.blogspot.com). The temporary mandatory injunction further requires the removal of any such documents posted at any web site; requires communication of this Order to anyone to whom these documents have already been disseminated, informing them of the terms of this Order; and enjoins the named individuals, organizations, and entities from posting information to websites to facilitate dissemination of these documents.[25]

LEGAL ARGUMENT

I. INTRODUCTION

This Court must enter an Order vacating CMO-3 by providing that the Documents should not be classified as confidential, as Lilly has classified them. Even if this Court is unwilling to

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[22] See Docket Entry 994 (emphasis added). Lilly's counsel did not tell the Times what additional information Lilly had that would be valuable to individuals taking Zyprexa.

[23] See Docket Entry 996.

[24] See Sharav Aff, ¶¶ 10-15.

[25] It does not appear that this document has been formally assigned a docket entry number as of today's date.

make this declaration, Ms. Sharav and AHRP must nevertheless be allowed to disseminate the Documents, as Lilly has failed to demonstrate that an injunction is proper under the three-prong test established in controlling case law. Specifically,

- The Injunction is not in the public interest, as any injunction must be. The important data in the Documents and the long history of cover-ups by "Big Pharma" make this clear.
- Lilly cannot show that the balance of hardships tips in its favor, as any party must do in order to be entitled to an injunction. The Documents were generated by Lilly itself and, if their disclosure is damaging, it is because the Documents reveal the Company's admissions about the risks of Zyprexa. On the other hand, the harm to the public in not having material information about the dangers of a particular drug is manifest.
- Finally, Lilly cannot show that it will be irreparably harmed in the absence of an injunction, as it is required to. The Times articles let the cat out of the bag, particularly in the Internet-dominated universe we inhabit today; no further "harm" will come to Lilly.[26] In addition, the Times still has the documents and Lilly has not asked this or any court to order the Times either to return them or to not publish them. They are, therefore, in the public domain.

[26] See, e.g., Suthers v. Amgen, Inc., 372 F. Supp. 2d 416, 423 (S.D.N.Y. 2005) (citing Brooks v. Giuliani, 84 F.3d 1454, 1462 (2d Cir. 1996); Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc., 596 F.2d 70, 72 (2d Cir. 1979)) (observing that "[i]n order to obtain a preliminary injunction the plaintiffs must show (a) irreparable harm and (b) either (1) likelihood of success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly in favor of the party seeking preliminary relief"); accord Capital Ventures Int'l v. Republic of Argentina, 443 F.3d 214, 223 n.7 (2d Cir. 2006) (citing Brody v. Vill. of Port Chester, 261 F.3d 288, 290 (2d Cir. 2001)) (observing that "district courts may consider potential effects on the public interest in determining whether to grant ... the preliminary injunction").

II. THIS COURT MUST VACATE CMO-3 INSOFAR AS IT SERVES TO PREVENT THE DISCLOSURE OF THE DOCUMENTS BY MS. SHARAV AND AHRP

I.

Under Federal Rule of Civil Procedure 26(c),

> [u]pon motion .... , and for good cause shown, the court in which [an] action is pending ... may make an order which justice requires to protect a party or a person ... , including one or more of the following:
>
> * * * *
>
> (7) that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way.[27]

Charles Alan Wright and Arthur Miller's well-known treatise on civil procedure makes clear that this rule "empowers the court to make a wide variety of orders for the protection of parties and witnesses in the discovery process." Wright and Miller go on to observe that "[o]nce entered, protective orders need not remain in place permanently, and they are not immutable in their terms." Thus, motions regarding protective orders may be made by any party, and a "third party may be allowed to intervene to contest the issuance of a protective order." Indeed, "[a]lthough requests for modification do frequently come from the litigants themselves, it is often true that they come from, or are made on behalf of, other persons."[28]

In Loussier v. Universal Music Group, Inc., the district court had occasion to consider the meaning of the phrase "good cause shown" in Rule 23(c). Judge Kimba Wood, ruling on a joint request that videotaped depositions of rappers Dr. Dre and Eminem be deemed confidential, opined as follows on what the drafters of the Rules of Civil Procedure intended by that phrase:

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[27] See Fed. R. Civ. Pro 12(c).

[28] See Charles Alan Wright, et al., Procedure for Obtaining Protective Orders and Modification of Protective Orders, 8 Fed. Prac. & Proc. Civ. 2d §§ 2035, 2044.1 (2006 Supp.) (citing Grove Fresh Distributors, Inc. v. Everfresh Juice Co., 24 F.3d 893 (7th Cir. 1994)); accord Fed. R. Civ. Pro. 26(c).

> While parties to litigation can agree among themselves what information, if any, they will not release to the public, the Court has the power to decide what material will ultimately be unavailable to the public. The reasons for this are clear. The inherent pressures of litigation will often provoke parties to consent to protective orders during discovery. Frequently, a party will agree to the opposing party's request for a protective order so as to expedite the discovery process and reduce the cost of litigation. There are plainly many incentives for parties to agree to a protective order, while there are few incentives for parties to oppose one. Moreover, a party consenting to a protective order will rarely, if ever, take into consideration the public's interest in such matters. In such cases, the good cause requirement [of Federal Rule of Civil Procedure 26(c)] acts as a guardian of the public's right of access to discovery documents by requiring parties to make a threshold showing before documents will be withheld from public view.[29]

The court, applying these principles, proceeded to deny the request, finding that the public interest was disserved by such a classification.[30] The same result should occur here.

Similarly, in a 1994 decision of the Seventh Circuit, the appellate panel determined that a stipulated protective order was improvidently issued by the district court because it failed to independently determine whether the requirements of Rule 26(c) were satisfied. The court further determined that the documents in question were not actually confidential.[31] In a Third Circuit decision issued the same year, Pansy v. Borough of Stroudsburg, the panel observed that "disturbingly, some courts routinely sign orders which contain confidentiality clauses without considering the propriety of such orders, or the countervailing public concerns which are sacrificed by such orders."[32]

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[29] See Loussier v. Universal Music Group, Inc., 214 F.R.D. 174, 177-78 (S.D.N.Y. 2003).

[30] See id.

[31] See, e.g., Jepson, Inc. v. Makita Elec. Works, Ltd., 30 F.3d 854 (7th Cir. 1994); accord Procter & Gamble Co. v. Bankers Trust Co., 78 F.3d 219 (6th Cir. 1996) (providing that a protective order under which the parties were given the discretion to determine which documents would be placed under seal, was improperly entered).

[32] See Pansy v. Borough of Stroudsburg, 23 F.3d 772, 785 (3d Cir. 1994); accord Aetna Cas. & Sur. Co. v. George Hyman Const. Co., 155 F.R.D. 113 (E.D.P.A. 1994) (rejecting a

Indeed, as Judge Weinstein stated in his book Individual Justice in Mass Tort Litigation,

> [p]rotective orders may have a legitimate role when there is no public impact or when true trade secrets are involved. But we can strike a fairer balance between privacy interests of corporations and the health and safety of the public. A publicly maintained legal system ought not protect those who engage in misconduct, conceal the cause of injury from the victims, or render potential victims vulnerable. Moreover, such secrecy defeats the deterrent function of the justice system.[33]

II.

In this matter, no reason exists for continuing to allow Lilly to classify the Documents as confidential. As reported by the Times, the documents consist of materials revealing that Lilly encouraged primary care physicians to use Zyprexa in patients who had neither schizophrenia nor bipolar disorder, that Lilly concealed the fact that Zyprexa causes significant weight gain and the onset of diabetes because Lilly knew that revealing these side effects would hurt existing and future sales of the drug, and that Lilly provided false data to prescribing doctors in an effort to boost sales. This information is not the type of information protected by Rule 26(c) because it does not consist of protected trade secrets, it does not consist of protected confidential research, and it does not consist of protected commercial information.

It is, rather, evidence of a pattern of misinforming the buying public so newsworthy that the Times took the extraordinary step of publishing stories about the import of the Documents for five straight days. Ms. Sharav wishes to publish the Documents themselves, and Mr. Cohen wishes to analyze and disseminate portions of the Documents in his scholarship, as scholars before him have done with documents generated by other drug manufacturers such as Pfizer and Warner-Lambert.

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stipulation allowing each party to designate documents as "confidential," as this resulted in "judicial discretion yielding to private judgment").

[33] See Jack B. Weinstein, Individual Justice in Mass Tort Litigation (Northwestern, February 2005), Page 70.

Lilly's only stated reason as to why the Documents should remain confidential notwithstanding the Times stories – that the Documents contain "incomplete information" that will cause "concern among patients that could cause them to stop taking their medication without consulting their physician" – does not pass muster. Lilly is able to post documents providing more "complete information," if any, on its web sites, take out advertisements clarifying its position, and issue press releases telling its side of the story. Lilly's explanation, which is essentially that it will sell less of a drug that it should sell less of if the Documents are posted, in actuality demonstrates why the Documents themselves should be released to the public.

We do not condone the violation of CMO-3. It must not be forgotten, however, that by designating the Documents as confidential, Lilly also violated CMO-3, which required Lilly to only designate as confidential the documents that it "in good faith believe[d]" were confidential. Documents evidencing, at best, the concealing of material information from or, at worst, intentionally misleading patients and prescribing physicians are not confidential by any standard. Moreover, whatever wrong was committed by the violation of CMO-3 pales in comparison to the wrong committed by Lilly as evidenced by these documents and the continuing wrong that would occur if the information in these documents does not see the light of day. Lilly has settled many of the cases brought by victims of Zyprexa for hundreds of millions of dollars, yet the company continues to take the public stance that the drug does not cause excessive weight gain or diabetes. The Documents prove otherwise.

III.

It is incumbent upon this Court to vacate CMO-3 in part by providing that the documents forming the subject of the Injunction are not confidential and by declaring that the dissemination of those documents by Ms. Sharav, AHRP, and Mr. Cohen does not violate any Order of this Court.

III. IN THE ALTERNATIVE, THIS COURT MUST DISSOLVE THE INJUNCTION INSOFAR AS IT SERVES TO PREVENT THE DISCLOSURE OF THE DOCUMENTS BY MS. SHARAV AND AHRP

It is axiomatic that "[i]njunctive relief should not be granted when it would operate inequitably or contrary to the justice of the case"; thus, in order to be entitled to an injunction, a litigant must demonstrate that the injunction is in the public interest, must demonstrate that the "balance of hardships" tips in its favor, and must demonstrate that it will be irreparably harmed in the absence of an injunction. As Lilly cannot make any of the three required showings, the Injunction must be dissolved.[34]

1. Lilly Cannot Demonstrate that the Public Interest is Served by the Extension of the Injunction

The public interest will be served by the dissemination of the Documents by Ms. Sharav, AHRP, and Mr. Cohen, just as it was served by the Times article, the YouTube video, and the prior scholarship on Pfizer and Warner-Lambert's internal documents. Similarly, the public interest will be disserved by Lilly's continued attempts to obfuscate the truths regarding Zyprexa from the public at large.

Lilly's stated basis for confidentiality – the supposed protection of the public – is actually the best evidence that no protective order should shield this information from public view. Lilly does not fear dissemination of these documents to its competitors who have time and again acted with similar disregard to revealing the adverse effects of pharmaceuticals. Instead, Lilly fears that existing and potential customers may choose not to buy Zyprexa if they are informed about the risks of the drug. This Court should not sanction such conduct. Patients and human subjects have a fundamental right to all information with respect to the risk and benefits of a drug or medical procedure before using the drug or undergoing the procedure. As Justice Benjamin N.

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[34] See, e.g., Brooks, 84 F.3d at 1454; accord Capital Ventures, 443 F.3d at 223 n.7; accord Richard B. Gallagher, et al., Injunctions, 42 Am. Jur. 2d Injunctions § 35 (May 2006 Supp.).

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Cardozo stated almost 100 years ago in establishing the principles of informed consent: "Every human being of adult years and sound mind has a right to determine what should be done with his own body."[35]

Lilly lacks any genuine argument that the public interest is served by an extension of the Injunction. The Injunction should not be extended.

2. Lilly Cannot Demonstrate that the "Balance of the Hardships" Tips in its Favor, Or that it Will Suffer Any Harm, Much Less Irreparable Harm

Lilly cannot demonstrate that it would suffer any undue harm if the public is able to view the Documents at this time, or that it will suffer any harm at all, much less irreparable harm, if the Injunction is extended.

The fact of the Documents, and a summary of their contents, was made known to the public through the Times' coverage. The public continues to have access to archives of the Times' coverage, roughly 10,000 web pages about the Times' coverage, the YouTube video, the Wikipedia entry, and countless other web and print resources about Lilly's malfeasance. Even if it could be said that "harm" would somehow befall Lilly if the actual Documents were disclosed, any such "harm" would be entirely attributable to Lilly's own admissions that it hid the risks of Zyprexa from the consuming public and their doctors and marketed the drug to a population that should not have taken it.

Ms. Sharav and Mr. Cohen are not ex-employees of Lilly who have stolen trade secrets. They are, respectively, a public health advocate and a professor who seek to share the text of Lilly's own words with the public. Both view exposing the type of information Lilly wants so desperately to keep hidden as their primary public role. The continuation of the Injunction would bear heavily on Ms. Sharav, AHRP, and Mr. Cohen without benefiting Lilly, and it must be dissolved.

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[35] See Schloendoerf v. Society of New York Hospital, 105 N.E. 92 (N.Y. 1914).

CONCLUSION

For the foregoing reasons, CMO-3 should be vacated as described above or, in the alternative, the Injunction should be dissolved as described above.

Respectfully Submitted,

SHERMAN, SILVERSTEIN, KOHL,
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Pennsauken, New Jersey
Monday, January 8, 2007

EXHIBIT "A"

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE ZYPREXA PRODUCTS LIABILITY LITIGATION	:	04-MD-1596

AFFIDAVIT OF VERA SHARAV

Vera Sharav, having been duly sworn, hereby says, states, and avers as follows, under penalty of perjury:

1. I am a public advocate for human rights.

2. My advocacy efforts have focused on human participants in unethical research experiments, as well as patients victimized by concealed drug hazards.

3. My work is widely followed. I have testified before a panel of experts at the Office of Human Research Protection, served on the Children's Workgroup of the National Human Research Advisory Committee, given testimony before national policy advisory panels, made presentations before the American Public Health Association, presented a paper on medical ethics before a United States military ethics forum, and spoken in academic forums at the University of Texas and Columbia University.

4. I am the author of articles appearing in Ethical Human Psychology and Psychiatry, Journal of Disability Policy Studies, and American Journal of Bioethics.

5. I head the AHRP, a not-for-profit national network of individuals dedicated to advancing responsible and ethical medical practices, as well as ensuring the human rights, dignity, and welfare of participants in the medical enterprise.

6. The AHRP disseminates, through the Internet, daily e-mails called Infomails.

7. The Infomails provide subscribers with information about medical research ethics and drug safety issues affecting vulnerable populations, such as children, the elderly, and people with cognitive or physical disabilities.

8. The Infomails have a wide following among patient advocacy organizations, members of the scientific community, public officials, the media, medical journal editors, and lawyers.

9. The AHRP also operates the web site ahrp.org and maintains a blog at ahrp.blogspot.com.

10. On or around December 15, 2006, an attorney named James Gottstein, who is the principal of a public interest law firm in Alaska devoted to defending people against forced psychiatric drugging, contacted me.

11. Mr. Gottstein advised me that, through the use of a Subpoena, he had come into possession of important documents regarding Zyprexa, a drug manufactured by Eli Lilly and Company ("Lilly") that is indicated for the treatment of schizophrenia and certain bipolar disorders (collectively, "Documents").

12. Mr. Gottstein then forwarded the Documents to me.

13. I have reviewed the Documents and believe, based upon my experience, that the Documents constitute invaluable primary sources that the public must have access to.

14. I further believe that Lilly designated the Documents as confidential in bad faith.

15. I, along with AHRP, wish to disseminate the original Documents through the use of AHRP's Infomails, AHRP's web site and blog, and other means.

16. I certify that the foregoing statements are true. I am aware that if any of the foregoing statements are false, I will be subject to penalty of perjury.

Vera Sharav

Sworn to me before this 8TH day of January 2007

Nicole L. Hilliard
Notary Public

NICOLE L HILLIARD
Notary Public, State of New York
No. 01HI6152886

EXHIBIT "B"

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE ZYPREXA PRODUCTS LIABILITY LITIGATION	:	04-MD-1596

AFFIDAVIT OF DAVID COHEN

David Cohen, having been duly sworn, hereby says, states, and avers as follows, under penalty of perjury:

1. I am a tenured, Full Professor of Social Work at Florida International University in Miami.

2. I hold a Ph.D. in Social Welfare from the University of California, Berkeley, a Master's in Social Work from Carleton University, and a Bachelor's in Psychology from McGill University.

3. My research and scholarly efforts have focused on how psychotropic medications such as antipsychotics, antidepressants, and stimulants are studied in clinical trials, approved by regulatory agencies, promoted by their manufacturers, prescribed by physicians, and used and experienced by patients.

4. I am the author or co-author of over 50 publications appearing in American Journal of Public Health, PLoS Medicine, Health, Virtual Mentor: Ethics Journal of the American Medical Association, Ethical Human Sciences and Services, American Journal of Psychiatry, The Encyclopedia of Psychology, Journal of Mind and Behavior, Social Work in Mental Health, and other peer-reviewed journals in medicine, psychiatry, law and psychiatry, psychology, social work, nursing, sociology, and social policy.

5. I am the co-author or co-editor of 12 books and monographs on withdrawal effects of psychotropic medications, adverse effects of antipsychotic drugs, medicalization,

consumer information and empowerment about psychotropic medication, and related topics. I am also author or co-author of over 20 book chapters on these and other related topics.

6. I have been investigator or co-investigator in about 25 research grants from governmental and other agencies in Canada and the United States, to conduct epidemiological, clinical, naturalistic, and social policy research. My latest grant was awarded by the U.S. Attorneys General Consumer and Prescriber Education Grant Program, for the purpose of teaching critical thinking skills about psychotropic medications (including the off-label uses of antipsychotic drugs such as Zyprexa) to non-medical mental health professionals.

7. I have presented the results of my research and scholarship in numerous regional, national, and international professional meetings, in grands rounds in departments of psychiatry and pediatrics, in schools of law, before consumer organizations, patient groups, and other scholarly, clinical, and professional conferences.

8. I teach graduate courses on psychopathology and on psychopharmacology to students in the health and social sciences.

9. I am a Licensed Clinical Social Worker in the State of Florida, where I practice counseling and psychotherapy, frequently around medication-related issues.

10. I am a member of the Board of Directors of Alliance for Human Research Protection (AHRP), a not-for-profit national network of individuals dedicated to advancing responsible and ethical medical practices, as well as ensuring the human rights, dignity, and welfare of participants in the medical research enterprise.

11. On or around December 20, 2006, I received by mail discs containing documents regarding Zyprexa, a drug manufactured by Eli Lilly and Company ("Lilly") that is indicated for the treatment of schizophrenia and certain bipolar disorders (collectively, "Documents").

12. The discs were sent by an attorney named James Gottstein, who is the principal of a public interest law firm in Alaska devoted to defending people against forced psychiatric drugging.

13. I have not attempted to disseminate the Documents in any way.

14. I have reviewed the Documents and believe, based upon my review, that they constitute invaluable information on how antipsychotic drugs are marketed to prescribing physicians, and that the public must be able to have access to these Documents in order to better grasp that known or likely risks and adverse effects of prescribed medications are not always fully disclosed by pharmaceutical companies either to regulatory agencies who approve these medications, to physicians who prescribe them, or to patients or their families who use them.

15. Thus, in the interests of the public's health and right to know what may harm it, these documents should not in my view remain confidential.

16. I further believe that Lilly designated the Documents as confidential in bad faith.

17. I wish to undertake analysis and dissemination of some information contained in the Documents, in the form of articles or other publications destined for professional or popular audiences, in accordance with the research and scholarly interests I have pursued for nearly two decades.

18. For example, an analysis of court documents available to the public from United States ex rel. David Franklin vs. Pfizer, Inc., and Parke-Davis, Division of Warner-Lambert Company was recently published as an article entitled "Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents," in Annals of Internal Medicine, 2006, Vol. 145, pages 284-293, by authors Michael A. Steinman, MD, Lisa A. Bero, PhD, Mary-Margret Chren, MD, and C. Seth Landfeld, MD. The authors and accompanying editorial about this article recognize that such documents constitute unique opportunities to understand how

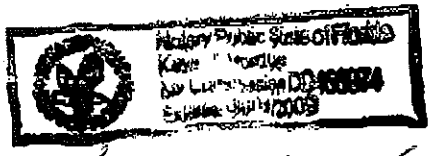
drugs are marketed to professionals and to the public and to be able to properly distinguish marketing from scientific activities. Being able to make such a distinction has large implications for the protection of public health, since commercial marketing activities are frequently disguised as scientific activities, a deliberate tactic which can mislead regulators, policymakers, health systems administrators, health professionals, and patients.

19. I certify that the foregoing statements are true. I am aware that if any of the foregoing statements are false, I will be subject to penalty of perjury.

David Cohen

Sworn before me this 8 day of January 2007

Notary Public



UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE ZYPREXA PRODUCTS LIABILITY LITIGATION	:	04-MD-1596

CERTIFICATE OF SERVICE

I, Alan C. Milstein, hereby certify that on the date indicated below, I served a copy of the within papers upon the following individuals:

Sean Fahey, Esquire, Pepper Hamilton, L.L.P. (via facsimile – 215-689-4642)
John McKay, Esquire (via facsimile – 907-272-5646)
Ted Chabasinski, Esquire (via facsimile – 541-345-3737)
Alex Reinbert, Koob & Magoolaghan (212-349-4658)
Kenneth Feinberg, Esquire, The Feinberg Group (via facsimile – 202-962-9290)
Melvyn Weiss, Milberg Weiss (via facsimile – 212-868-1229)

Respectfully Submitted,

SHERMAN, SILVERSTEIN, KOHL,
ROSE & PODOLSKY, P.A.

By: _____
Alan C. Milstein

/s/ Alan C. Milstein

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Pennsauken, New Jersey
Monday, January 8, 2007