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UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA LITIGATION

No. 07-CV-0504 (JBW)

**NONPARTIES MINDFREEDOM INTERNATIONAL, JUDI CHAMBERLIN,  
ROBERT WHITAKER, VERA SHARAV, DAVID COHEN, ALLIANCE FOR  
HUMAN RESEARCH PROTECTION, AND JOHN DOE'S JOINT PROPOSED  
FINDINGS OF FACT AND OBJECTIONS TO ELI LILLY'S AMENDED  
PROPOSED FINDINGS OF FACT EXHIBITS A - D**

# **EXHIBIT A**

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

**FILED**  
IN CLERK'S OFFICE  
U.S. DISTRICT COURT, E.D.N.Y.  
★ JAN 05 2007 ★  
BROOKLYN OFFICE

-----X  
In re: ZYPREXA PRODUCTS LIABILITY : MDL No. 1596  
LITIGATION :  
-----X

THIS DOCUMENT RELATES TO:

ALL ACTIONS

:  
: **ORDER FOR TEMPORARAY**  
: **MANDATORY INJUNCTION**  
:  
-----X

Upon consent of members of the In Re Zyprexa Product Liability Litigation Plaintiffs' Steering Committee ("PSC"), Eli Lilly and Company, and all interested parties appearing before this Court, it is hereby

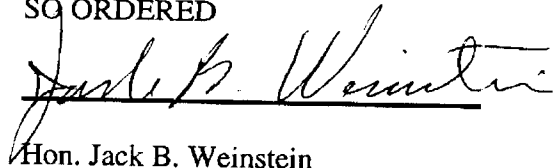
ORDERED that the Joint Motion for a Temporary Mandatory Injunction entered December 29, 2006 is extended <sup>to January 16, 2007,</sup> and the following individuals, entities, and organizations (and any related individuals, entities or organizations) who have received documents produced by Eli Lilly and Company (including all copies of any electronic documents, hard copy documents and CDs/DVDs) are hereby enjoined from further disseminating these documents: Terri Gottstein, Jerry Winchester, Dr. Peter Breggin, Dr. Grace Jackson, Dr. David Cohen, Bruce Whittington, Dr. Stephen Kruszewski, Laura Ziegler, Judi Chamberlin, Vera Sherav, Robert Whittaker, Will Hall, Eric Whalen (and [www.joysoup.net](http://www.joysoup.net)), MindFreedom (and [www.mindfreedom.org](http://www.mindfreedom.org)), the Alliance for Human Research Protection (and [www.ahrp.org](http://www.ahrp.org) and [www.ahrp.blogspot.com](http://www.ahrp.blogspot.com)) and [zyprexa.pbwiki.com](http://zyprexa.pbwiki.com). This temporary mandatory injunction further requires the removal of any such documents posted at any website; 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.

*JAC*

*[Handwritten signature]*

This injunction shall remain in full force and effect until January 16, 2007, at which time the Honorable Jack B. Weinstein will hear further argument from the interested parties.

SQ ORDERED

A handwritten signature in black ink, appearing to read "Jack B. Weinstein", written over a horizontal line.

Hon. Jack B. Weinstein  
United States District Judge

Dated: January 4, 2007  
Brooklyn, New York

# **EXHIBIT B**

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

**FILED**  
IN CLERK'S OFFICE  
U.S. DISTRICT COURT, E.D.N.Y.

★ JAN 29 2007 ★

In re: ZYPREXA  
PRODUCTS LIABILITY LITIGATION

ORDER

BROOKLYN OFFICE

THIS DOCUMENT RELATES TO:  
ALL ACTIONS

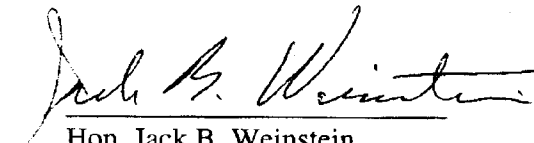
04-MDL-1596

JACK B. WEINSTEIN, Senior United States District Judge:

A motion to declassify documents that are the subject of this court's preliminary injunction of January 4, 2007, and to modify the protective order under which those documents were classified, has been made by parties subject to the injunction. The parties shall arrange with case manager June Lowe, who can be reached at (718) 613-2525, to set a date for argument of this motion after the pending injunction proceedings, and related contempt actions, if any, have been completed.

The brief filed in support of the motion will also be treated as a submission in the pending injunction proceedings.

SO ORDERED.

  
Hon. Jack B. Weinstein

Date: January 25, 2007  
Brooklyn, N.Y.

*dl*

# **EXHIBIT C-1**

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 MODIFYING CMO-3 IN PART**

**INTRODUCTION**

On January 4, 2007, Vera Sharav, the Alliance for Human Research Protection (“AHRP”), and David Cohen were enjoined from disseminating approximately 700 documents regarding the drug Zyprexa (collectively, “Documents”). The Documents, like almost all of the hundreds of thousands of documents produced by Eli Lilly and Company (“Lilly”) during the course of this litigation, were designated as confidential by Lilly pursuant to Case Management Order 3, a protective order entered on August 9, 2004 (“CMO-3”). As reported in The New York Times, the Documents reveal that Lilly encouraged primary care physicians to use Zyprexa in patients who had neither schizophrenia nor bipolar disorder, Lilly concealed two side effects of Zyprexa – significant weight gain and diabetes – because Lilly knew that disclosing these side effects might hurt existing and future sales of the drug, and Lilly provided false data to prescribing doctors in an effort to boost sales. Lilly had absolutely *no cause*, much less the good cause required by Federal Rule of Civil Procedure 23(c), to classify the Documents as confidential and, thus, acted in bad faith. The dissemination of the Documents is critical to the health, safety, and welfare of the general public. By and through their attorney, Alan C. Milstein of Sherman, Silverstein, Kohl, Rose & Podolsky, P.A., Ms. Sharav, AHRP, and Mr. Cohen respectfully seek an Order modifying CMO-3 by determining that the Documents are not confidential and may be disseminated freely at this time.



## 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.<sup>1</sup>

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, public officials, the media, medical journal editors, and lawyers. The AHRP also operates the web site [ahrp.org](http://ahrp.org) and maintains a blog at [ahrp.blogspot.com](http://ahrp.blogspot.com).<sup>2</sup>

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

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<sup>1</sup> See Affidavit of Vera Sharav ("Sharav Aff."), attached as Exhibit "A," ¶¶ 1-4.

<sup>2</sup> See Sharav Aff, ¶¶ 4-9.

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.<sup>3</sup>

## II.

The Documents had been designated as confidential by Lilly pursuant to CMO-3, which was entered at the outset of this case.<sup>4</sup> CMO-3 gives Lilly the unfettered right to designate documents as confidential, as long as Lilly “in good faith believes” that they are confidential.<sup>5</sup> The terms of CMO-3 may have been the subject of serious discussion between Lilly and the plaintiffs’ attorneys, and even the Court. Once entered, however, no such discussions ensued with respect to whether a class of documents should be marked “confidential.” Lilly took this as a license to mark all of them as “confidential.” Pursuant to the terms of CMO-3, once Lilly designates a document as confidential, the document cannot be disseminated to any member of the general public.<sup>6</sup>

The paragraph governing “permissible disclosures of confidential discovery material” allows for the dissemination of the confidential documents to litigation counsel (¶ 6.a.), in-house counsel (¶ 6.b.), court officials (¶ 6.c.), any person designated by the Court “in the interest of justice” (¶ 6.d.), certain in-house paralegals (¶ 6.e.), certain plaintiffs’ lawyers (¶ 6.f.), certain additional outside counsel (¶ 6.g.), individuals being deposed (¶ 6.h.), expert witnesses (¶ 6.i.),

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<sup>3</sup> See Affidavit of David Cohen (“Cohen Aff.”), attached as Exhibit “B,” ¶¶ 1-5.

<sup>4</sup> See Docket Entry 61 (CMO-3).

<sup>5</sup> See Docket Entry 981.

<sup>6</sup> See Docket Entry 61.

certain employees of counsel (¶ 6.j.), employees of third-party contractors (¶ 6.k.), and certain employees and former employees (¶ 6.l.) – but not the plaintiffs or their physicians. Thus, neither the plaintiffs nor their physicians had access to the Documents, though their secrecy may have contributed to the harm of thousands of consumers of Zyprexa.<sup>7</sup>

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.<sup>8</sup> 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.”<sup>9</sup> 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

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<sup>7</sup> See Docket Entry 61, ¶ 6.

<sup>8</sup> See Docket Entry 61.

<sup>9</sup> See Cohen Aff., ¶ 13.

Promotion of Gapapentin: 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 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.<sup>10</sup>

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.<sup>11</sup>

### 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.<sup>12</sup> 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.<sup>13</sup>

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

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<sup>10</sup> See Cohen Aff., ¶¶ 16-17.

<sup>11</sup> See Sharav Aff., ¶¶ 10-15.

<sup>12</sup> See Docket Entries 991-995 (containing print-outs of the articles).

<sup>13</sup> See [en.wikipedia.org/wiki/New\\_York\\_Times](http://en.wikipedia.org/wiki/New_York_Times) (visited January 4, 2007).

Zyprexa – significant weight gain and the onset of diabetes – because Lilly knew that disclosing 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.<sup>14</sup> 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.<sup>15</sup>

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.<sup>16</sup>

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.<sup>17</sup> 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

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<sup>14</sup> See Docket Entries 991-995.

<sup>15</sup> See Docket Entries 991-995.

<sup>16</sup> 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.

<sup>17</sup> See [youtube.com/watch?v=nj0LZZzrcrs&mode=related&search=](http://youtube.com/watch?v=nj0LZZzrcrs&mode=related&search=) (visited January 4, 2007); see also [ridgewayng.com](http://ridgewayng.com) (visited January 4, 2007) (containing information on Pharmed Out).

timely video about Zyprexa (olanzapine), an antipsychotic drug approved by the FDA to treat schizophrenia and bipolar disorder. 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.<sup>18</sup>



#### 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.<sup>19</sup> The Documents should no longer be kept from public view.

The edition of the British Medical Journal (“BMJ”) published on January 13, 2007, subsequent to the entry of the Injunction, contains an article entitled “Drug Company Tries to Suppress Internal Memos.” The article reveals that Eli Lilly, in an e-mail to the BMJ, stated that it is pursuing action against Mr. Gottstein and Dr. Egilman because “these individuals have violated a federal court order by leaking the documents” and further stated that it has not released

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<sup>18</sup> See [ridgewayng.com](http://ridgewayng.com).

<sup>19</sup> See Docket Entry 981.

its internal documents publicly because the company “has no intention of violating [CMO-3] by releasing documents ourselves.”<sup>20</sup> If Lilly was being ingenuous to the BMJ and truly wished to release to the public the Documents and other internal documents generated during the litigation process, it would have withdrawn its request for an Injunction.

Instead, Lilly continued to press on ceaselessly. A hearing on the Injunction was held before Judge Weinstein on January 16-17, 2007. At that time, the Court took testimony from attorney Richard D. Meadows of the Lanier Law Firm, who serves as lead counsel to a number of plaintiffs in this case. Mr. Meadows testified that, during the course of the Zyprexa litigation, Lilly produced hundreds of thousands of documents, and it designated virtually all of these documents as confidential. Lilly was so indiscriminate in its classification of documents that it marked documents patently of public record – such as articles that had been published in prominent newspapers and correspondence between Lilly and the FDA – as confidential without regard to whether the information contained in any given document constituted a trade secret or other information protected by Rule 26(c). Mr. Meadows further testified that a number of plaintiffs suffered from the very conditions revealed by the documents – obesity and diabetes – and would have not have suffered such harm if either they or their physicians had access to the information contained in the Documents.

**LEGAL ARGUMENT: THIS COURT MUST ENTER AN ORDER MODIFYING CMO-3 BY PROVIDING THAT THE DOCUMENTS ARE NOT CONFIDENTIAL**

I.

Federal Rule of Civil Procedure 5(d) originally required all discovery materials to be filed with the Clerk’s office to be available for public view. Although that Rule has been modified in the interests of conserving court resources, a court may still require such filing upon

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<sup>20</sup> A copy of this article is on file with the Court.

the request of a nonparty who desires access to public records. Federal Rule of Civil Procedure 26(c), which governs the entry of protective orders in the federal courts, provides:

[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.<sup>21</sup>

As this Court has held, the Federal Rules thus presume that discovery materials such as the documents in this case are open to the public.<sup>22</sup> Charles Alan Wright and Arthur Miller's well-known treatise on civil procedure makes clear that, while Rule 26(c) "empowers the court to make a wide variety of orders for the protection of parties and witnesses in the discovery process, . . . [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."<sup>23</sup>

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

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<sup>21</sup> See Fed. R. Civ. Pro 26(c). In Seattle Times Co. v. Rhinehart, 467 U.S. 20 (1984), the Supreme Court upheld a constitutional challenge to Rule 26(c), determining that the First Amendment to the United States Constitution does not require open access to materials exchanged during discovery.

<sup>22</sup> In Re "Agent Orange" Product Liability Litigation, 104 F.R.D. 559 (E.D.N.Y. 1984).

<sup>23</sup> 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 Martindell v. Int'l Telephone and Telegraph Co., 594 F.2d 291, 296 n.7 (2d Cir. 1979).



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:

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.<sup>24</sup>

The court, applying these principles, proceeded to deny the request, finding that the public interest was disserved by such a classification.<sup>25</sup> 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.<sup>26</sup> 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

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<sup>24</sup> See Loussier v. Universal Music Group, Inc., 214 F.R.D. 174, 177-78 (S.D.N.Y. 2003).

<sup>25</sup> See id.

<sup>26</sup> 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).

sacrificed by such orders.”<sup>27</sup> Judge Weinstein echoed these sentiments in his book Individual Justice in Mass Tort Litigation, observing that

[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.<sup>28</sup>

The leading district court decision regarding protective orders, In Re “Agent Orange” Product Liability Litigation, was authored in the mid-1980’s by then-Magistrate Judge Shira A. Scheindlin and adopted as the Opinion of the Court by then-Chief Judge Weinstein.<sup>29</sup>

In that matter, during the course of settlement proceedings in the “Agent Orange” litigation, the Vietnam Veterans of America intervened in the action “for public access to much of the discovery material produced by the defendants and the Government over the last five years [of the litigation].” One of the non-representative members of the class intervened as well, seeking “access to all the documents produced during discovery as well as all depositions.”<sup>30</sup>

The material in question was sealed pursuant to a number of protective orders entered in the litigation. One such protective order, PTO-19, protected from disclosure medical records on file with the Veterans Administration, on the ground that disclosure would endanger the privacy and livelihoods of the individuals mentioned in those records. A subsequent protective order, PTO-42, shielded from public view the records of the Environmental Protection Agency

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<sup>27</sup> 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 stipulation allowing each party to designate documents as “confidential,” as this resulted in “judicial discretion yielding to private judgment”).

<sup>28</sup> See Jack B. Weinstein, Individual Justice in Mass Tort Litigation (Northwestern, February 2005), Page 70.

<sup>29</sup> See In Re “Agent Orange” Product Liability Litigation, 104 F.R.D. 559 (E.D.N.Y. 1984).

<sup>30</sup> See id. at 562 (emphases deleted).

regarding “Agent Orange,” on the ground that “an agency review of each document, for claims of privilege or confidentiality in advance of production, would have created inordinate delay and expense.” The most encompassing protective order, issued a few years later, “required that all documents produced by any party and all depositions were to be treated confidentially.” The issuing judge’s stated rationale was that good cause for the order existed because of the “complexity of the litigation, the emotionalism surrounding the issues, [and] the number of documents ... to be reviewed,” among other reasons. This protective order was modified somewhat by later protective orders, but essentially remained in place.<sup>31</sup>

In reviewing the continued propriety of those protective orders, this Court began its analysis by noting that Rule 26(c) requires that “the proponent of non-disclosure prove that good cause exists to limit public access to discovery material,” and, “in the absence of such proof, the discovery is open to the public.” It determined that the following standard regarding the modification of protective orders should apply:

Given that proceedings should normally take place in public, imposing a good cause requirement on the party seeking modification of a protective order is unwarranted. If access to protected fruits can be granted without harm to legitimate secrecy interests, or if no such interests exist, continued judicial protection cannot be justified. In that case, access should be granted even if the need for the protected materials is minimal. When that is not the case, the court should require the party seeking modification to show why the secrecy interests deserve less protection than they did when the protective order was entered. Even then, however, the movant should not be saddled with a burden more onerous than explaining why his need for the materials outweighs existing privacy concerns. ... If access to the discovery materials here will cause no harm to legitimate secrecy interests under Rule 26(c), then there is no further justification for the protective orders. If the release of such materials would cause actual harm, then plaintiffs must show why the secrecy interests deserve less protection than they did when the order was granted.

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<sup>31</sup> See *id.* at 562-63.

Applying these standards, this Court lifted its prior protective orders,<sup>32</sup> as it should do again here.

## II.

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.<sup>33</sup> 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 information revealed in the litigation process. Such protective orders, like CMO-3, which 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.

In this matter, no reason exists for continuing to allow Lilly to classify the Documents as confidential. Lilly willy-nilly designated every document that it produced as confidential. Thus, any after-the-fact claim by Lilly that the Documents are "truly" confidential must be viewed in the light of Lilly's prior bad-faith conduct.

Regardless of how Lilly attempts to classify the Documents, the public's need for the Documents far outweighs any alleged privacy interests on the part of Lilly. As reported by the

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<sup>32</sup> See *id.* at 570-72.

<sup>33</sup> See e.g., [moralgroup.com/NewsItems/Drugs/p3.htm](http://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](http://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).

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. These are not documents Lilly wants to shield from its competitors; rather, Lilly wants to conceal the information contained in these Documents from prospective customers – patients and their physicians who are entitled to such information in order to make an informed decision as to whether to pursue a certain course of treatment.

The Documents evidence a pattern of misinforming the buying public so important to the public interest 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.

Indeed, as the injunction hearing was taking place, state prosecutors in Illinois and Vermont demanded that Lilly produce these and other documents which reveal how the company promoted the drug off-label.<sup>34</sup>

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<sup>34</sup> See <http://www.nytimes.com/2007/01/20/business/20drug.html>.

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, including its nascent site zyprefacts.com, 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. Mr. Meadows testified that a number of plaintiffs suffered from the very conditions revealed by the documents – obesity and diabetes – and would have not have suffered such harm had either they or their physicians had access to the information contained in the Documents.

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. The case for disclosure here is even more compelling than the case for disclosure in “Agent Orange,” as disclosure in this case will serve to protect the public from future injuries, rather than simply allow the public to understand why past injuries had occurred. In addition, and as consistent with the recent actions of the attorney generals of Vermont and Illinois, public access to the documents is critical to an understanding of how Lilly, like other big pharmaceutical companies, markets its products off-label in violation of FDA regulations and of the public trust.

III.

This Court should thus modify CMO-3 in part by providing that the documents produced by Lilly which are the subject of the Injunction are not confidential and should be available for public view.

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 22, 2007

# **EXHIBIT C-2**



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](http://ahrp.org) and maintains a blog at [ahrp.blogspot.com](http://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").

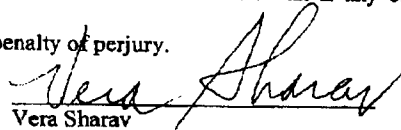
12. Mr. Gottstein then forwarded the Documents to me.

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 8<sup>TH</sup> day of January 2007

  
Notary Public

NICOLE L. HILLIARD  
Notary Public, State of New York  
No. 01186192888



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## 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 grand 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

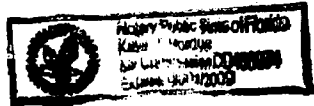
drugs are marketed to professionals and to the public and to be able to properly distinguish marketing from scientific activities. Being able to make such a distinction has large implications for the protection of public health, since commercial marketing activities are frequently disguised as scientific 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  
David Cohen

Sworn before me this 8 day of January 2007

Kevin T. Haidul  
Notary Public



Kevin T. Haidul  
Comm # DD456974  
exp. 8/1/09

# **EXHIBIT D**



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Attorney for non-party John Doe

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA PRODUCTS LIABILITY  
LITIGATION

No. 04-MDL-01596 (JBW)

NOTICE OF MOTION AND MOTION FOR  
RECONSIDERATION OR IN THE  
ALTERNATIVE FOR STAY PENDING  
APPEAL

This Notice of Motion and Motion for Reconsideration or, in the alternative, for Stay Pending Appeal, is brought by John Doe, who is not a party to the above-captioned action. Doe contributes to the website located at <http://zyprexa.pbwiki.com> (the "Wiki").<sup>1</sup> This Court's January 4, 2007, Order for Temporary Mandatory Injunction (the "January 4 Order") names the Wiki as one of the entities enjoined from publishing "documents produced by Eli Lilly and Company" and from "posting information to...facilitate dissemination of these documents."

Doe submits this short motion pursuant to the oral invitation of the Court to join in the hearing set by this Court for January 8, 2007, at 2 p.m. EST regarding the January 4 Order. Doe

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<sup>1</sup> While he is not a party to this action, John Doe himself has personal experience with psychiatric misdiagnosis and, accordingly, would prefer to remain anonymous. The right to speak anonymously is clearly protected by the First Amendment. *See, e.g., McIntyre v. Ohio Elections Comm'n*, 514 U.S. 334 (1995). By this motion, Doe hereby seeks leave to remain anonymous for purposes of vindicating his rights as a nonparty. *See Roe v. Aware Woman Ctr. for Choice, Inc.*, 253 F.3d 678, 684-685 (11th Cir. 2001) (recognizing right to litigate anonymously where private information is at stake).

was not served with notice nor otherwise informed of this Court's proceedings prior to the issuance of the January 4 Order.

Doe respectfully requests that the Court reconsider and clarify its January 4 Order for two reasons: (1) as applied to nonparty Doe, the Order is beyond the Court's injunctive authority; and (2) as applied to nonparty Doe, the Order constitutes an unconstitutional prior restraint on speech in violation of the First Amendment.

Doe therefore asks the Court to clarify that its January 4 Order does not bind nonparties such as Doe who are not legally identified with, nor acting in concert with, a party or any other person bound by this Court's Case Management Order No. 3 ("CMO-3"). In the alternative, Doe requests that the Court stay its January 4 Order pending appellate review.

### **BACKGROUND**

John Doe is an individual who has an interest in mental health care issues. In late December 2006, he became aware of the existence of the Wiki, a website located at <http://zyprexa.pbwiki.com>, where individuals interested in the controversy surrounding Zyprexa could collaboratively publish information relating to it. The Wiki is noncommercial; Doe and the other contributors volunteer their time and effort as citizen-journalists. In order to participate in the public debate regarding Zyprexa, Doe has published information on the Wiki, including links to other websites purporting to offer copies of internal Eli Lilly documents relating to the subject of the articles that appeared recently in *The New York Times* (the "Lilly Documents").

The Wiki is an example of a new, flourishing, collaborative publishing medium on the Internet. Unlike typical websites, a "wiki" is a website that permits visitors themselves to easily add, remove, and otherwise revise the content of the website on an ongoing basis.<sup>2</sup> Wikis thus

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For more on the history and characteristics of wikis, see Wiki, Wikipedia,

foster dynamic, collaborative authorship and publication of information to a global audience on the World Wide Web. The Wiki that Doe contributed to here is one of more than 100,000 wikis that are hosted by an online service known as “pbwiki,” which allows anyone to start and edit a wiki for free.<sup>3</sup>

Thanks to the work of a variety of contributors, including Doe, the Wiki is today one of the most comprehensive and up-to-date public sources of information regarding the controversy surrounding Zyprexa. Contributors to the Wiki have never posted any copies of the Lilly Documents on it, but the Wiki has in the past included links to other websites and Internet sources that purported to have copies available for download. On December 29, 2006, an attorney for Eli Lilly sent an email to pbwiki demanding the immediate deletion of the Wiki, citing this Court’s prior orders relating to the Lilly Documents, none of which mentioned the Wiki.<sup>4</sup> Since becoming aware of this Court’s January 4 Order, contributors to the Wiki have amended it to remove all links to the Lilly Documents, as well as other information that might “facilitate dissemination of these documents.” The Wiki currently remains available in this edited state.<sup>5</sup>

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<<http://en.wikipedia.org/wiki/Wiki>>.

<sup>3</sup> Just as anyone interested in starting a “blog” can do so by visiting Google’s Blogger.com, so too anyone interested in starting a wiki can do so by visiting <<http://pbwiki.com>>.

<sup>4</sup> The email was dated December 29, 2006, sent by Sean P. Faheys, Esq., of Pepper Hamilton LLP, and read in its entirety as follows: “The pbwiki listed above is facilitating the unlawful sharing of copyright protected material, and breach of a Federal Court order. Please shut it down immediately, and delete all cached material.” The same day, the email was forwarded by pbwiki personnel to Doe.

<sup>5</sup> Although changing the content of the Wiki requires the use of a password, the password has been made available in a variety of public locations on the Internet. Accordingly, Doe is only one of an unknown number of individual contributors to the Wiki. Consequently, there is no way that Doe (or any other contributor) can guarantee that links do not reappear on the Wiki. Nevertheless, in an effort to comply with the Court’s January 4 Order, Doe has done what he can to remove links on the Wiki to the Lilly Documents as he becomes aware of them.

Doe has no connection to any party in this litigation, nor has he, to the best of his knowledge, had any communication with any person who is subject to CMO-3. As an interested member of the public, however, and in light of the importance of the revelations contained in the recent *New York Times* articles regarding the Lilly Documents, Doe believes continued public access to and analysis of the Lilly Documents is vital to a full public understanding of the medical, ethical, and health issues relating to Zyprexa. Accordingly, he would like to continue to post links to the Lilly Documents to the Wiki, in order to further contribute to and participate in the public discussion of these important issues.

The information that Doe desires to publish on the Wiki (including links to sites where the Lilly Documents can be obtained) plainly relate to a matter of overriding public concern. According to *The New York Times*, the Lilly Documents reveal a pattern of unlawful activities by Eli Lilly that may have left the 20 million individuals who have taken Zyprexa with incomplete information regarding the side effects of the drug. This matter is also an urgent one: the thousands of doctors and patients that are making daily decisions regarding the prescribing and use of Zyprexa stand to benefit from the information Doe would like to post to the Wiki. In addition, the national debate regarding Zyprexa is happening in the press right now, making this information particularly time-sensitive.

#### **ARGUMENT**

**The Court Lacks the Authority to Bind Nonparties Acting Independently of Those Who are Subject to this Court's Protective Orders.**

Rule 65(d) of the Federal Rules of Civil Procedure provides:

Every order granting an injunction and every restraining order...is binding only upon the parties to the action, their officers, agents, servants, employees, and attorneys, and upon those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise.

As the Second Circuit has recognized, “Rule 65(d) codifies the well-established principle that, in exercising its equitable powers, a court ‘cannot lawfully enjoin the world at large.’” *People of N.Y. v. Operation Rescue Nat’l*, 80 F.3d 64, 70 (2d Cir. 1996) (quoting J. Learned Hand in *Alemite Mfring Corp. v. Staff*, 42 F.2d 832, 832 (2d Cir. 1930)); accord *Regal Knitwear Co. v. N.L.R.B.*, 324 U.S. 9, 14 (1945) (recognizing F.R.C.P. 65(d) as an expression of common law doctrine defining scope of a court’s equitable powers).

Accordingly, in order for a nonparty to be bound by an injunction, “that entity must either aid and abet the defendant or be legally identified with it.” *Paramount Pictures Corp. v. Carol Publishing Group, Inc.*, 25 F.Supp.2d 372, 374 (S.D.N.Y. 1998); accord *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 112 (1969) (“[A] nonparty with notice cannot be held in contempt until shown to be in concert or participation.”); *People of N.Y. v. Operation Rescue*, 42 F.3d at 70 (injunctions reach a nonparty only where the nonparty abets or is legally identified with a party); *Vuitton et Fils S.A. v. Carousel Handbags*, 592 F.2d 126, 129 (2d Cir. 1979) (refusing to enjoin nonparty until “acting in concert” is proven).

In other words, a court may not enjoin nonparties who are acting independently. In *Paramount Pictures v. Carol Publishing*, 25 F.Supp.2d 372 (S.D.N.Y. 1998), for example, a copyright owner obtained an injunction against an infringer barring the further distribution of a book entitled *The Joy of Trek*. When asked to extend the injunction to nonparty distributors and retailers who had already received copies of the book from the defendant, the court refused, holding that its injunctive powers could not reach “independent action taken by nonparties on their own behalf.” *Id.* at 375. In reaching this conclusion, the court noted that “[b]ecause a court’s power to enjoin is limited to the conduct of a party, it is the relationship between the party enjoined and the nonparty that determines the permissible scope of an injunction.” *Id.* at

374; accord *Alemite Mfring*, 42 F.2d at 833 (“Thus, the only occasion when a person not a party may be punished, is when he has helped to bring about, not merely what the decree has forbidden, but what it has the power to forbid, the act of a party.”). The court reached this conclusion despite the risk that these independent actions might result in further infringements of the copyright owner’s rights. *Id.* at 375-76.

In light of these authorities, this Court’s January 4 Order sweeps too broadly when it purports to enjoin nonparties, including the Wiki and its contributors, from disseminating or “facilitat[ing] dissemination” of the Lilly Documents. As a contributor to the Wiki, Doe is acting entirely independently, without any relationship to any party in this litigation or any person bound by CMO-3. Neither Eli Lilly nor any other party to the litigation has produced any evidence suggesting otherwise. *See People of N.Y. v. Operation Rescue*, 80 F.3d at 70 (burden of showing that a nonparty is within the scope of an injunction lies with party seeking enforcement). Accordingly, this Court may not enjoin Doe’s publication on the Wiki of information relating to the Lilly Documents, including information intended to facilitate dissemination of the documents.

**II. The Court’s January 4 Order Constitutes an Unconstitutional Prior Restraint on Speech in Violation of the First Amendment.**

The Court’s January 4 Order is additionally improper because, as drafted and as applied to Doe, it is a prior restraint on speech in violation of the First Amendment. “[P]rior restraints on speech and publication are the most serious and the least tolerable infringement on First Amendment rights.” *Nebraska Press Ass’n v. Stuart*, 427 U.S. 539, 559 (1976). Accordingly, any prior restraint “bears a heavy presumption against its constitutional validity.” *U.S. v. Quattrone*, 402 F.3d 304, 310 (2d Cir. 2005). Furthermore, “[a] prior restraint is not constitutionally inoffensive merely because it is temporary.” *Id.*

In *Proctor & Gamble Co. v. Bankers Trust Co.*, 78 F.3d 219 (6th Cir. 1996), the court addressed a situation very nearly identical to the situation that now faces the Court. In that case, *Business Week*, which was not a party to the underlying civil dispute between two corporate litigants, obtained documents from the litigation that were subject to a protective order. *Id.* at 222. Without affording *Business Week* prior notice or an opportunity to be heard, the district court issued a series of temporary injunctions forbidding the magazine from publishing the documents. *Id.* at 222-23. Subsequently, the district court held a hearing inquiring into the manner in which *Business Week* came into possession of the documents and issued a permanent injunction against publication. *Id.*

On appeal, the Sixth Circuit concluded that all of the injunctions were impermissible prior restraints on pure speech in violation of the First Amendment. *Id.* at 225-27. The court held that a party seeking even a temporary injunction against pure speech must establish that “publication [would] threaten an interest more fundamental than the First Amendment itself.” *Id.* at 227. While admitting that restrictions on the dissemination of information obtained in discovery may be permissible against parties, *see Seattle Times v. Rhinehart*, 467 U.S. 20 (1984), the court held that similar restrictions on independent nonparties is impermissible, *see Proctor & Gamble*, 78 F.3d at 225. Moreover, the court noted that although brief injunctions to facilitate judicial deliberation are generally proper, “when that approach results in a prior restraint on pure speech by the press it is not allowed.” *Id.* at 226; *accord In re Providence Journal Co.*, 820 F.2d 1342, 1351 (1st Cir. 1986). Also deemed impermissible were injunctions designed to enable inquiry into how the documents were obtained or whether *Business Week* personnel were aware of the protective order: “[w]hile these might be appropriate lines of inquiry for a contempt proceeding or criminal prosecution, they are not appropriate bases for issuing a prior restraint.”

*Id.* at 225. In addition, the issuance of the original injunction *ex parte* was error: “there is no place for such orders in the First Amendment realm where no showing is made that it is impossible to serve or notify the opposing parties and give them an opportunity to participate.” *Id.* at 226 (internal quotation omitted).

The circumstance presented here is very nearly on all fours with *Proctor & Gamble*. The Court’s January 4 Order, issued *ex parte* without notice to Doe, purports to forbid him from publishing the Lilly Documents or “posting information...to facilitate dissemination of these documents.” This prohibition targets pure speech based on the content of the speech, and thus constitutes a prior restraint. *See U.S. v. Quattrone*, 402 F.3d at 309 (defining prior restraint as a “judicial order that suppresses speech...on the basis of the speech’s content and in advance of its actual expression.”). Neither Eli Lilly nor any other party has established that publication of the enjoined material would imperil “an interest more fundamental than the First Amendment itself.” *Proctor & Gamble*, 78 F.3d at 227.

That the medium of expression here is the Internet does not change the analysis. *See Ford Motor Co. v. Lane*, 67 F.Supp.2d 745 (E.D. Mich. 1999) (applying *Proctor & Gamble* to reject prior restraint on website). Wikis are a part of the Internet’s “vast platform from which to address and hear from a world wide audience of millions of readers, viewers, researchers and buyers.” *ACLU v. Reno*, 521 U.S. 844, 852 (1997); *see also id.* at 870 (finding “no basis for qualifying the level of First Amendment scrutiny that should be applied to this medium.”). Although the Wiki is not a commercial news outlet, nor Doe a professional journalist, these facts also do not change the analysis. *See Bridge C.A.T. Scan Assoc. v. Technicare Corp.* 710 F.2d 940, 946 (2d Cir. 1983) (“[T]he First Amendment,...in addition to freedom of the press, also guarantees freedom of speech.”); *Ford v. Lane*, 67 F.Supp.2d at 753 (“[W]hile the reach and



power of the Internet raises serious legal implications, nothing in our jurisprudence suggests that the First Amendment is circumscribed by the size of the publisher or his audience.”).

Whether discussion, publication, or dissemination of the Lilly Documents may implicate other legal rights enjoyed by Eli Lilly is also irrelevant here. First, because Eli Lilly has not asserted any such rights in the underlying action, this Court has no basis for protecting those interests by issuing orders against nonparties. *See Bridge C.A.T. Scan*, 710 F.2d at 946 (“[A]ny issue as to trade secrets was completely collateral to the underlying dispute, and the court had no basis for granting [injunctive] relief as an incident to any rights asserted in the action.”); *Paramount Pictures*, 25 F.Supp.2d at 375-76 (refusing to expand injunction to reach nonparties despite likelihood of copyright infringement). Second, a party’s sensitivities regarding its trade secrets and other commercial interests do not outweigh the First Amendment’s abhorrence of prior restraints on pure speech. *See Proctor & Gamble*, 78 F.3d at 225 (“The private litigants’ interest in protecting their vanity or their commercial self-interest simply does not qualify as a grounds for imposing a prior restraint.”); *Ford v. Lane*, 67 F.Supp.2d at 750 (rejecting prior restraint against a party, even where likelihood of trade secret misappropriation had been shown).

In light of the overriding public concern in the information that Doe desires to publish on the Wiki (including links to sites where the Lilly Documents can be obtained), and the fact that the national debate on Zyprexa is taking place in the press right now, *see In re Providence Journal*, 820 F.2d at 1351 (“News is a constantly changing and dynamic quantity. Today’s news will often be tomorrow’s history.”), the issuance of even a temporary prior restraint against Doe gravely offends the fundamental purposes of the First Amendment.

### **III. The Court Should Clarify the Scope of Its January 4 Order.**

In light of the preceding arguments, Doe respectfully asks that the Court clarify the scope of its January 4 Order, *see Paramount Pictures*, 25 F.Supp.2d at 374 (“It is undoubtedly proper for a district court to issue an order clarifying the scope of an injunction....”), by striking “zyprexa.pbwiki.com” from its January 4 Order.<sup>6</sup> This would lift the prior restraint against Doe, while leaving intact the restriction on persons subject to CMO-3, who are already prohibited from disseminating the Lilly Documents on the Wiki or in any other medium.

Even with this clarification, Doe remains concerned that Eli Lilly will use this Court’s Order in its efforts improperly to censor the Lilly Documents off the Internet. As mentioned above, counsel for Eli Lilly had—prior to the January 4 Order—already sent an email to pbwiki demanding complete deletion of the Wiki. In order to forestall this censorial misuse of this Court’s orders in the future, Doe respectfully asks this Court to add the following clarification to its January 4 Order:

“Notwithstanding the foregoing, this Order only binds nonparties who have notice of this Order and (a) are legally identified with a party or person directly bound by CMO-3; or (b) are in active concert with, participating with, or aiding and abetting a party or person directly bound by CMO-3. Nothing in this Order restrains independent actions taken by nonparties on their own behalf.”

This additional language simply restates the outer legal limit of this Court’s authority, and may help dispel any improper chilling effect that the Order may have when delivered to third parties (such as pbwiki.com).

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<sup>6</sup> The preceding arguments would appear to apply with equal force to the other 4 websites named in the January 4 Order to the extent they are not acting in concert with, or legally identified with, a party bound by CMO-3. The undersigned counsel does not represent any other individual or entity mentioned in the January 4 Order, and thus cannot presume to speak on their behalf. Nevertheless, if the Court adopts the clarification suggested herein, the changes should vindicate the free speech rights of all those named in the January 4 Order.

Finally, Doe respectfully requests that the Court add the following additional language to its January 4 Order:

“In addition, Eli Lilly is hereby enjoined from representing to any third party that this Order prohibits anyone other than those enjoined above from disseminating any documents produced by the Eli Lilly and Company.”

This language is necessary to prevent Eli Lilly and its counsel from misusing this Court’s Order to chill protected speech by invoking the Order in cease-and-desist letters sent to individuals and intermediaries. As described above, Eli Lilly has already shown a willingness to do just that.<sup>7</sup>

The Court should not permit its Orders to be misused in this manner. The proposed additional language is intended to afford the Court contempt power over Eli Lilly should it continue to do so.

Finally, if the Court denies this request for reconsideration and clarification of its January 4 Order, Doe respectfully requests that the Court stay the order as applied to any nonparty not legally identified with, acting in concert with, in participation with, or aiding and abetting, a person bound by CMO-3 pending appellate review of the Order.

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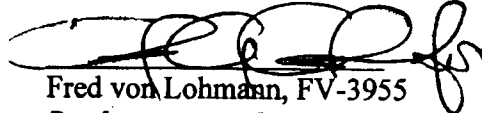
<sup>7</sup> Eli Lilly is, of course, entitled to send cease-and-desist notices invoking other sources of legal authority, subject to applicable legal limits. *See Online Policy Group v. Diebold, Inc.*, 337 F.Supp.2d 1195 (N.D. Cal. 2004) (copyright owner not entitled to send notices invoking the DMCA where activity clearly qualifies as a fair use).

**CONCLUSION**

For the reasons above, Doe asks that the Court reconsider and clarify its January 4 Order or, in the alternative, stay its Order pending appellate review.

Date: January 9, 2007

Respectfully submitted,



Fred von Lohmann, FV-3955  
*Pro hac vice application pending*  
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(415) 436-9333 x123  
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*Attorney for nonparty John Doe*

## CERTIFICATE OF SERVICE

*In re: Zyprexa Products Liability Litigation*

I, Cindy Cohn, am over the age of eighteen years and am not a party to the within action. I am employed in the County of San Francisco, CA.

On the date set forth below, following ordinary business practices, the following documents described as:

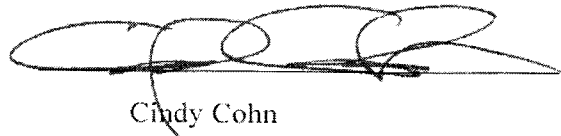
1. Notice of Motion and Motion of Non-Party John Doe for Reconsideration or in the Alternative for Stay Pending Appeal.

were sent via facimile and email at the offices of my employer, ELECTRONIC FRONTIER FOUNDATION, located at 454 Shotwell Street, San Francisco, CA 94110 to:

1. Nina M. Gussak, Pepper Hamilton LLP (215) 981-4307  
(gussackn@pepperlaw.com)
2. William M. Audet, Alexander Hayes and Audet LLP (415) 576-1776  
(waudent@alexanderlaw.com)
3. James M. Shaughnessy, Milberg Weiss & Bershad LLP (212) 868-1229  
(jshaughnessy@milbergweiss)

I declare under penalty of perjury under the laws of the State of California and New York that the foregoing is true and correct and that this declaration was executed on this day in San Francisco, California.

DATE: 1/7/07



Cindy Cohn