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.[1]

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 and maintains a blog at ahrp.blogspot.com.[2]

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

[2] 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.[3]

II.

The Documents had been designated as confidential by Lilly pursuant to CMO-3, which was entered at the outset of this case.[4] CMO-3 gives Lilly the unfettered right to designate documents as confidential, as long as Lilly "in good faith believes" that they are confidential.[5] The terms of CMO-3 my 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.[6]

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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[3] See Affidavit of David Cohen ("Cohen Aff."), attached as Exhibit "B," ¶¶ 1-5.
[4] See Docket Entry 61 (CMO-3).
[5] See Docket Entry 981.
[6] 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.[7]

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.[8] 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."[9] 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.
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> 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

[7] See Docket Entry 61, ¶ 6.
[8] See Docket Entry 61.
[9] 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.[10]

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.[11]

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.[12] 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.[13]

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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[10] See Cohen Aff., ¶¶ 16-17.
[11] See Sharav Aff., ¶¶ 10-15.
[12] See Docket Entries 991-995 (containing print-outs of the articles).
[13] See 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.[14] 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.[15]

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.[16]

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.[17] 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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[14] See Docket Entries 991-995.

[15] See Docket Entries 991-995.

[16] 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.

[17] 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).

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.[18]

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.[19] 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

[18] See ridgewayng.com.

[19] See Docket Entry 981.

its internal documents publicly because the company "has no intention of violating [CMO-3] by releasing documents ourselves."[20] 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

[20] 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:
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> * * * *
>
> (7) that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way.[21]

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. [22] 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."[23]

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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[21] 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.

[22] In Re "Agent Orange" Product Liability Litigation, 104 F.R.D. 559 (E.D.N.Y. 1984).

[23] 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.[24]

The court, applying these principles, proceeded to deny the request, finding that the public interest was disserved by such a classification.[25] 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.[26] 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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[24] See Loussier v. Universal Music Group, Inc., 214 F.R.D. 174, 177-78 (S.D.N.Y. 2003).

[25] See id.

[26] 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."[27] 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.[28]

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.[29]

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."[30]

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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[27] 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").

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

[29] See In Re "Agent Orange" Product Liability Litigation, 104 F.R.D. 559 (E.D.N.Y. 1984).

[30] 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.[31]

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.

[31] See id. at 562-63.

Applying these standards, this Court lifted its prior protective orders,[32] 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.[33] 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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[32] See id. at 570-72.

[33] 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).

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.[34]

[34] 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 zyprexafacts.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.

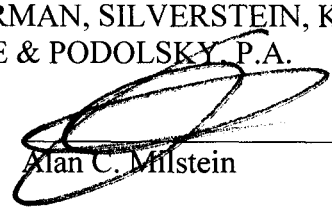
Lilly has settled many of the cases brought by victims of Zyprexa for hundreds of millions of dollars, yet the company continues to take the public stance that the drug does not cause excessive weight gain or diabetes. The Documents prove otherwise. The case for disclosure here is even more compelling 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: 
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