UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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IN RE: ZYPREXA PRODUCTS LIABILITY LITIGATION

04-MDL-1596 (JBW)

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NOTICE OF MOTIONS OF THE U.S. PSYCHIATRIC REHABILITATION ASSOCIATION, MENTAL HEALTH AMERICA, CONSUMERS UNION, FORMER MENTAL HEALTH COMMISSIONERS, AND INDIVIDUAL MENTAL HEALTH PROFESSIONALS TO INTERVENE AND TO CONTEST CONFIDENTIALITY DESIGNATIONS

TO: ALL COUNSEL OF RECORD

PLEASE TAKE NOTICE that upon the attached papers, the proposed intervenors will move this Court before the Honorable Jack B. Weinstein at the United States Courthouse for the Eastern District of New York, at a date and time specified by the Court, for an Order permitting them to intervene for the purpose of challenging Eli Lilly and Company's confidentiality designation of certain documents, and for a ruling that Lilly

has failed to meet its burden of proving that "good cause" exists for nondisclosure of the documents.

Respectfully submitted,

/s/
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Attorneys for Intervenors

February 7, 2007

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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IN RE: ZYPREXA PRODUCTS LIABILITY LITIGATION

04-MDL-1596 (JBW)

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MOTIONS OF THE U.S. PSYCHIATRIC REHABILITATION ASSOCIATION, MENTAL HEALTH AMERICA, CONSUMERS UNION, FORMER MENTAL HEALTH COMMISSIONERS, AND INDIVIDUAL MENTAL HEALTH PROFESSIONALS TO INTERVENE AND TO CONTEST CONFIDENTIALITY DESIGNATIONS AND MEMORANDUM OF LAW IN SUPPORT THEREOF

INTRODUCTION AND SUMMARY OF ARGUMENT

In late December of 2006, the *New York Times* published three articles discussing internal documents of Eli Lilly and Company (Lilly) that raised substantial concerns about the side effects of Zyprexa and about Lilly's marketing of that drug. The December 17 article stated that, based on "hundreds of internal Lilly documents and e-mail messages among top company managers," Lilly had "engaged in a decade-long effort to play down the health risks of Zyprexa." Alex Berenson, *Eli Lilly Said to Play Down Risk of Top Pill*, N.Y. TIMES, Dec. 17, 2006 (hereinafter Berenson, *Lilly Said to Play Down Risk*).

The December 18 article, citing "internal Lilly marketing materials," stated that Lilly illegally "encouraged primary care physicians to use Zyprexa," which had been approved by the FDA only for schizophrenia and bipolar disorder, "in patients who did not have either condition." Alex Berenson, *Drug Files Show Maker Promoted Unapproved Use*, N.Y. TIMES, Dec. 18, 2006 (hereinafter Berenson, *Drug Files Show*).

The December 21 article, again citing "company documents," stated that "[f]or at least a year, Eli Lilly provided information to doctors about the blood-sugar risks of its drug Zyprexa that did not match data that the company circulated internally when it first reviewed its clinical trial results." Alex Berenson, *Disparity Emerges in Lilly Data on Schizophrenia Drug*, N.Y. TIMES, Dec. 21, 2006 (hereinafter Berenson, *Disparity Emerges*).

The documents that formed the basis for the three *New York Times* stories had been provided by Lilly to Plaintiffs' counsel in discovery in this litigation pursuant to a protective order, Case Management Order No. 3 (CMO-3). They became public after they were obtained by James Gottstein, an Alaska attorney, by a subpoena in an unrelated case to Dr. David Egilman (a Plaintiffs' expert in this litigation). The documents were subsequently posted on several websites. After the documents became public, Lilly contended that Egilman had violated CMO-3, and that Gottstein had aided and abetted that violation. This Court responded with a series of orders.[1]

Intervenors - who include the Mental Health America (formerly the National Mental Health Association), the U.S. Psychiatric Rehabilitation Association (USPRA), Consumers Union, several former State mental health commissioners, and individual

[1] On December 18, this Court enjoined Gottstein from further dissemination of any documents produced by Lilly pursuant to CMO-3, and required Gottstein to return any such documents to Special Master Woodin and to take steps to retrieve any such documents that he gave to third parties. On December 29, this Court issued a temporary mandatory injunction requiring 12 additional individuals, and their related entities and organizations, to remove any of the discovery documents from their websites and barring them from further disseminating the documents. On January 4, 2007, this Court extended the December 29 injunction to reach one additional individual, two specifically named organizations (MindFreedom and the Alliance for Human Research Protection), and four websites (www.joysoup.net, www.ahrp.org, www.ahrp.blogspot.com, and zyprexa.pbwiki.com).

mental health professionals - have had no involvement in any aspect of the factual disputes in this case. They take no position on whether Gottstein's actions in obtaining and disseminating the discovery materials were proper, or on whether this Court's injunctive power reaches third parties who played no role in obtaining the materials from individuals covered by CMO-3.

Instead, Intervenors contend that the documents should no longer be kept confidential by this Court.[2] Those documents cannot satisfy the requirements of Rule 26(c)(7) of the Federal Rules of Civil Procedure if they do not contain "trade secrets or other confidential research, development, or commercial information," and — especially given the strong public interest in informing the two million Zyprexa users and their clinicians of the side effects of this medication — there is no "good cause" for keeping them secret even if they did contain confidential information. Accordingly, pursuant to Paragraph 9(b) of CMO-3, as well as Rule 24 of the Federal Rules of Civil Procedure, the Intervenors seek to intervene "to dispute [the] designation of [those] discovery materials as Confidential." CMO-3 ¶ 9(b).[3]

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[2] Intervenors have not seen the documents themselves, and base their contentions that the documents should be disclosed on the *New York Times*' descriptions of their contents. It is possible that some of the documents may contain information that should remain confidential under Rule 26. Accordingly, it may be necessary for the Court to make individualized determinations to decide which, if any, documents should remain secret.

[3] Paragraph 9(b) of CMO-3 states that an aggrieved party wishing to challenge a designation of confidentiality shall provide written notice to the designating party, identifying the specific Bates numbers of the documents in dispute, and that the designating party must respond within 20 days. If the parties are unable to resolve the dispute amicably, the designating party may move the Court for a ruling that the documents in question need not be disclosed under Rule 26(c)(7). Intervenors do not have access to any of the documents designated as confidential and thus cannot provide written notice identifying specific documents. Intervenors do, however, know the topics of many of these documents based on articles written by the *New York Times* and believe

INTERVENORS

The proposed Intervenors include psychiatrists and other mental health clinicians, researchers, former State mental health commissioners, consumer groups, and people with mental illness and their family members, all of whom have significant health and safety interests in obtaining access to the documents at issue so that they can make informed decisions about whether to take and/or prescribe Zyprexa. The Intervenors are as follows:

Paul J. Barreira, M.D., is Associate Professor of Psychiatry at Harvard Medical School. He is also the Director of Behavioral Health and Academic Counseling at Harvard University Health Services, where he oversees Harvard's mental health services, academic counseling, drug and alcohol services, Center for Wellness and Health Communication, and Office of Sexual Assault Prevention and Response. Additionally, Dr. Barreira is the Director of Waverley Place, a community psychiatric rehabilitation program of McLean Hospital in Belmont, Massachusetts. Earlier in his career, Dr. Barreira was the Deputy Commissioner and Medical Director of the Massachusetts Department of Mental Health. Dr. Barreira has a longstanding interest in the development and improvement of systems of care for delivering mental health services in the public and private sectors and, more recently, in university communities. His research interests include systems of care for co-occurring mental illness substance abuse, effectiveness of psychiatric rehabilitation programs, and evaluation of college mental

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they are not entitled to protection under Fed. R. Civ. P. 26(c)(7). As the Court has already directed Lilly to provide the basis for the confidentiality designations of the documents covered by the CMO-3, Intervenors have proceeded directly with this submission and have simultaneously provided Lilly with written notice of their objection

health services.

Joseph Bevilacqua, Ph.D., has twenty-one years of experience as State Commissioner of Mental Health Services in Virginia, South Carolina, and Rhode Island. He also served for four years as Assistant Commissioner for Community Services in Virginia. Prior to his state government service, Dr. Bevilacqua served in the United States Army as a social work officer working in psychiatric hospitals and Mental Health Clinics both in the states and overseas. Throughout his career, Dr. Bevilacqua has been actively affiliated with a number of academic institutions, including appointments at the University of Virginia, Brown University, Medical College of Virginia, University of South Carolina, and Medical University of South Carolina. He has also written a number of publications in the field of mental health. During his commissionerships, Dr. Bevilacqua served two terms as President of the National Association of State Mental Health Program Directors. He currently serves on the Board of Directors of the Human Services Research Institute in Boston, Massachusetts.

Consumers Union (CU) is a nonprofit organization founded in 1936 to promote a fair, just, and safe marketplace for all consumers. CU publishes *Consumer Reports* and *ConsumerReports.org* in addition to two newsletters, *Consumer Reports on Health* and *Consumer Reports Money Adviser* with combined subscriptions of more than 7 million. CU also has several public education websites and nearly 400,000 online participants who help to promote legislative and marketplace solutions to protect consumers' interests. CU has a strong interest in ensuring public access to complete information about the potential risks and benefits of prescription drugs.

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to the designations.

Ronald Davidson, Ph.D., has been Director of the Mental Health Policy Program at the University of Illinois at Chicago's Department of Psychiatry since 1994. Prior to that, he was Associate Clinical Director of the Illinois State Psychiatric Institute (ISPI), Interim Director of the Illinois Institute for Juvenile Research (IJR), and Vice-President/Director of Public Policy for the Mental Health Association in Illinois. In his various roles with the Illinois Department of Mental Health (at ISPI and IJR), he was administratively responsible for the operation of three state psychiatric hospitals for children. As a consultant for both the State of Illinois and the federal government, he has conducted over 400 reviews of psychiatric hospitals and residential treatment centers in 12 states. Dr. Davidson is a clinical psychologist, specializing in child and adolescent mental health policy, who received his doctoral degree in clinical psychology from the University of California, Davis, in 1982.

Paul G. Gorman, Ed. D., is the President and Chief Executive Officer of West Central Behavioral Health, a community mental health center that is part of the Dartmouth-Hitchcock Alliance. Dr. Gorman's career spans thirty years of involvement in management of mental health systems in both the public and private sectors. He was the Director of Mental Health, Substance Abuse and Developmental Services for the State of New Hampshire, and served as the Superintendent of New Hampshire Hospital (NHH), the public psychiatric hospital in New Hampshire. He was the Director of the West Institute at the New Hampshire-Dartmouth Psychiatric Research Center, an institute dedicated to developing and evaluating implementation strategies for evidence-based practices for people with severe mental illness. He also was the Director of Outpatient Services for the Human Resource Institute, a private psychiatric hospital in Boston,

Massachusetts. Dr. Gorman has served on a number of boards, including the board of the National Association of State Mental Health Program Directors' Research Institute.

Mental Health America (MHA), formerly the National Mental Health Association, is the country's oldest and largest nonprofit mental health organization. MHA has over 320 affiliates who are dedicated to improving the mental health of all Americans, especially the 54 million people who have severe mental disorders. Through advocacy, education, research, and service, MHA helps to ensure that people with mental illness are accorded respect, dignity, and the opportunity to achieve their full potential. Many of MHA's members have been or will be prescribed Zyprexa, and would benefit significantly from a full public debate and analysis of the information contained in the documents designated "Confidential" by Lilly.

Thomas Romeo was Director of Rhode Island's statewide agency for mental health for 12 years. With the support of four Governors, the Rhode Island State Legislature, and many citizens, he established a system of services based upon individual needs and with the ultimate goal being return to one's home community.

David J. Rothman, Ph.D., is the Bernard Schoenberg Professor of Social Medicine and the Director of the Center on Medicine as a Profession at the College of Physicians and Surgeons, Columbia University. Dr. Rothman is a leading expert on social medicine, the history of medicine, and medical conflicts of interest. His published works include *Conscience and Convenience: The Asylum and Its Alternatives in Progressive America* (1980); *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision-making* (1991); *Beginnings Count: The Technological Imperative in American Health Care* (1997); and, most recently, *Trust Is*

Not Enough: Bringing Human Rights to Medicine (with Sheila M. Rothman, 2006). Under the auspices of a project co-sponsored by the American Board of Internal Medicine Foundation, Dr Rothman has written an analysis of federal guidelines for physician-pharmaceutical industry exchanges and has developed recommendations for controlling conflicts of interest at academic medical centers. In the January 25, 2006 issue of the *Journal of the American Medical Association,* Dr. Rothman co-authored an article on health industry practices that create conflicts of interest, calling for greater disclosure and more stringent regulation of doctor/industry ties.

Elyn R. Saks, J.D., is the Orrin B. Evans Professor of Law, Psychology, Psychiatry, and the Behavioral Sciences at the Gould School of Law, University of Southern California (USC). She also teaches at the Institute of Psychiatry and the Law at the Keck School of Medicine at USC and is an adjunct professor of psychiatry at the University of California, San Diego. Professor Saks specializes in mental health law, criminal law, and children's law. Her recent publications include *Refusing Care: Forced Treatment and the Rights of the Mentally* Ill (University of Chicago Press, 2002), *Interpreting Interpretation: The Limits of Hermeneutic Psychoanalysis* (Yale University Press, 1999), and *Jekyll on Trial: Multiple Personality Disorder and Criminal Law* (with Stephen H. Behnke, New York University Press, 1997). Professor Saks' professional memberships include the Los Angeles Psychoanalytic Foundation, the Robert J. Stoller Foundation, the American Law Institute, and the American Psychoanalytic Association (affiliate membership).

The United States Psychiatric Rehabilitation Association (USPRA) is dedicated to the promotion, protection, and improvement of services that facilitate the

adjustment of persons with psychiatric disabilities into communities. Its members, who number nearly 1,400 across the country, include mental health practitioners, psychiatric rehabilitation agencies, and interested organizations and individuals. USPRA has nearly thirty state chapters. Both alone and in concert with the broader association, these chapters provide members with educational opportunities, advocate for state legislative and regulatory changes, and promote the development of leadership within the field of psychiatric rehabilitation.

ARGUMENT

I. Intervenors are Aggrieved Entities Who Should be Allowed to Intervene

Intervenors seek to challenge Lilly's confidentiality designations of documents pursuant to the process set forth in CMO-3. To "expedite the flow of discovery material," CMO-3 provides that the parties, not the Court, shall be initially responsible for designating documents "Confidential." *See* CMO-3 preamble, ¶¶ 3, 4. A party's designation of documents as "Confidential" does not mean that the Court concurs in the designation. Rather, pursuant to the process set up in Paragraph 9 of CMO-3, discovery materials retain confidential status only until a party or "aggrieved entity permitted by the Court to intervene for such purpose" challenges the designation; if the challenge cannot be resolved amicably, the party who designated the materials "Confidential" must file a motion with this Court, which will decide whether those materials "are entitled to [confidential] status and protection under Rule 26 of the Federal Rules of Civil Procedure." CMO-3 ¶ 9(b), (c). Intervenors invoke this process to challenge Lilly's designation of documents as "Confidential."

The proposed intervenors are clearly "aggrieved entities" within the meaning of CMO-3. As discussed in detail below, a key factor in determining whether "good cause" exists for keeping documents confidential is whether public interest requires disclosure. According to the *New York Times* articles, the documents at issue detail a decade-long campaign by Lilly to minimize the health risks of Zyprexa, as well as Lilly's more recent efforts to encourage primary care physicians to prescribe off-label use of the drug. As prominent mental health clinicians, researchers, academicians, and consumer groups, the proposed intervenors clearly have significant health and safety interests in obtaining access to the documents at issue. Their professional and personal experiences will provide the Court with a unique perspective on the public interests at stake in this case.

Even apart from the terms of the Case Management Order, intervention is appropriate pursuant to Rule 24 of the Federal Rules of Civil Procedure. Both this Court and the Second Circuit have made clear that Rule 24 provides an appropriate vehicle for nonparties to intervene for the limited purpose of challenging the designation of discovery materials as "Confidential" pursuant to a protective order. *See Martindell v. International Tel. & Tel. Corp.*, 594 F.2d 291, 293 - 295 (1979); *In re Visa Check/MasterMoney Antitrust Litig.*, 190 F.R.D. 309, 312 (E.D.N.Y. 2000); *see also Jessup v. Luther*, 227 F.3d 993, 997 (7th Cir. 2000) ("[E]very court of appeals to have considered the matter has come to the conclusion that Rule 24 is sufficiently broad-gauged to support a request of intervention for the purposes of challenging confidentiality orders"). Accordingly, Intervenors respectfully request that the Court grant their motion to intervene to challenge the confidentiality designations here.

II. Lilly Cannot Show That the Documents Should Remain Confidential

Both the Federal Rules of Civil Procedure and the protective order place the burden squarely on Lilly to prove that the documents should be kept confidential. Paragraph 9(c) of CMO-3 specifically states that "[t]he designating party shall have the burden of proof . . . to establish the propriety of its Confidential designation." And Paragraph 3 of the Order specifically ties the definition of "Confidential Discovery Materials" to Rule 26(c)(7) of the Federal Rules of Civil Procedure. CMO-3 ¶ 3. Rule 26(c)(7) states in pertinent part as follows:

> Upon motion by a party or by the person from whom discovery is sought, . . . and for good cause shown, the court . . . may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, 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 . . .

As the Second Circuit has repeatedly held, a party seeking to designate documents as confidential under Rule 26(c) must prove that they satisfy the requirements of the rule. *See, e.g.*, *Gambale v. Deutsche Bank AG*, 377 F.3d 133, 142 (2d Cir. 2004) ("[T]he party seeking a protective order has the burden of showing that "good cause" exists for issuance of that order.") (internal quotation marks omitted) (quoting *In Re Agent Orange Product Liability Litigation*, 821 F.2d 139, 145 (2d Cir. 1987), *cert. denied*, 484 U.S. 953 (1987)); *see also Citicorp v. Interbank Card Ass'n*, 478 F. Supp. 756, 765 (S.D. N.Y. 1979) ("[T]hose who seek to avoid disclosure of commercial information by a protective order under Rule 26(c) of the Federal Rules of Civil Procedure bear a heavy burden of demonstrating that disclosure will work a clearly defined and very serious injury.") (internal quotation marks omitted).

To establish that the documents at issue should remain confidential under Rule 26(c)(7), Lilly must satisfy two requirements. First, it must show that the designated documents contain "a trade secret or other confidential research, development or commercial information." Second, even if Lilly satisfies that first hurdle, it still must show that "good cause" exists for a protective order. "As with most evidentiary and discovery privileges recognized by law, there is no absolute privilege for trade secrets and similar confidential information." *Federal Open Market Comm. v. Merrill*, 443 U.S. 340, 362 (1979) (internal quotation marks omitted). "To demonstrate good cause under this provision, the party seeking the protective order must show that the information sought is a trade secret or other confidential information, and that the harm caused by its disclosure outweighs the need of the party seeking the disclosure." *Chembio Diagnostic Systems, Inc. v. Saliva Diagnostic Systems, Inc.*, 236 F.R.D. 129, 136 (E.D.N.Y. 2006). Based on the information available in the public record, Lilly cannot satisfy either prong of its burden of proof.

A. The Documents Do Not Contain Trade Secrets or Other Confidential Information

Lilly has not demonstrated that all of the material designated as "Confidential" pursuant to CMO-3 contains trade secrets or other confidential information protected by Rule 26(c)(7). Courts have defined confidential information under Rule 26(c)(7) to include information about such things as pricing, profits, costs, overhead, manufacturing specifications, and customer lists. *Vesta Corset Co., Inc. v. Carmen Foundations, Inc.*, No. 97 CIV. 5139 (WHP), 1999 WL 13257 (S.D.N.Y. Jan. 13, 1999); *see also Jazz Photo Corp. v. United States*, 439 F.3d 1344, 1358 (Fed. Cir. 2006) (confidential information

includes importer's "entry documents and information relating to its customers, suppliers, manufacturing processes, financial condition, and the quantity and value of its imports"). A trade secret may consist of any formula, pattern, device, or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. *Lehman v. Dow Jones & Co., Inc.*, 783 F.2d 285, 297 (2d Cir. 1986).[4]

In its pleadings to date, Lilly has not specified which documents it contends are confidential. Instead, it has stated only that virtually none of the designated documents should be disclosed. Lilly has relied solely on generalized statements that the pharmaceutical industry is extremely competitive and that the documents would give Lilly's competitors insight into its "structure, decision tree, internal workings, and processes for implementation of strategies" and give them advantages in dealing with physicians. Lilly's Jan. 31, 2007 Memorandum of Points and Authorities, at 10-11. Lilly makes no attempt to explain how disclosure of any particular type of document might bring about these alleged harms. Indeed, even its expert affidavit, while asserting the highly competitive nature of the pharmaceutical industry — and the value that *any* information might have to its competitors — is silent on any specific harm that would be caused by releasing the particular documents at issue. That is clearly not the level of proof contemplated by Rule 26(c)(7) or by the Protective Order — or, indeed, by this

[4] For additional examples of trade secrets and confidential business information, see *Sigma Chemical Co. v. Harris*, 794 F.2d 371 (8th Cir. 1996) (supplier capabilities); *Rivendell Forest Prod. Ltd. v. Georgia-Pacific Corp.*, 28 F.3d 1042 (10th Cir. 1994) (computer programs); *SI Handling Systems, Inc. v. Heisley*, 753 F.3d 1244, 1260 (3d Cir. 1985) (pricing methods).

Court as recently as three weeks ago. At the January 17, 2007 hearing, the Court directed Lilly, in its January 31 briefing, to "be precise on which documents" and to "be very specific" as to which of the documents "constitute trade secrets or embarrassment or the other language under the rules and how their release has harmed [Lilly]." Transcript of Hearing before the Honorable Jack B. Weinstein (January 17, 2007) at 242, line 20 – 243, line 17, attached to this Motion as Exhibit # 1.

Even without examining the documents, it is clear that much (if not all) of the information they contain does not constitute trade secrets or confidential business information. According to the *New York Times*, the documents include, among other things:

- A February 2000 memorandum reporting clinical trial results that showed that patients taking Zyprexa "were 3.5 times as likely to experience high blood sugar levels as those taking a placebo" — findings that were at odds with "the results that Lilly eventually provided to doctors until at least late 2001," which "indicated that patients taking Zyprexa were only slightly more likely to suffer high blood sugar as those taking a placebo," Berenson, *Disparity Emerges*, *supra*;

- A November 1999 study examining 70 clinical trials that found "that 16 percent of patients taking Zyprexa for a year gained more than 66 pounds" — findings that were at odds with the results Lilly publicly disclosed, "from a smaller group of clinical trials that showed about 30 percent of patients gained 22 pounds," *id.*;

- A 2000 email message "from one Lilly manager to another," which stated that "unless we come clean on this [potential link between Zyprexa and diabetes], it could get much more serious than we might anticipate," Berenson, *Lilly Said to Play Down*, *supra*;

- Lilly marketing research from 2000 and 2002 that "found that psychiatrists were consistently saying that many more of their patients developed high blood sugar or diabetes while taking Zyprexa than other antipsychotic drugs," *id.*;

- A March 2002 email from a Lilly manager that "rejected plans to give psychiatrists guidance about how to treat diabetes, worrying that doing so would tarnish Zyprexa's reputation," *id.*;

- Internal Lilly marketing studies showing that primary care physicians, who became the target of Lilly's advertising campaign, "were less aware of Zyprexa's side effects," *id.*;

- A document, from 1999 or 2000, in which a Lilly marketing executive stated that "dementia should be first message" of a campaign to market Zyprexa to primary care doctors, even though the drug had not been approved for dementia, Berenson, *Drug Files Show*, *supra*;

- Packets for Lilly sales representatives, prepared for the "Viva Zyprexa" campaign, that used the profile of an individual with mild dementia as an example to be discussed with doctors of a patient whom Zyprexa would help, *id.*;

- A 2001 email from a Virginia doctor to Lilly and the FDA complaining about a sales representative's use of that hypothetical profile, *id.*;

- A 2002 guide for Lilly sales representatives that used the profile of an individual with bipolar depression as an example of a patient whom Zyprexa would help, "even though Zyprexa has been approved only for the treatment of mania in bipolar disorder, not depression," *id.*

To the extent this material is accurately characterized by the *New York Times*, none of it is the type of proprietary information contemplated by Rule 26(c)(7) as trade secrets or other confidential business information.

To be sure, Lilly clearly does not want this material disclosed. That is hardly a surprise. The *New York Times* articles suggest that the company actively sought to conceal evidence that its largest-selling drug has a significant risk of severe side effects, and that the company marketed the drug for unapproved uses. But the disclosure of that information could hardly create unfair advantages for Lilly's competitors. Unlike trade secrets (which often must be protected lest competitors seek to use them in their own business), or confidential business information (which often must be protected lest

competitors seek to copy a company's business processes or identify weaknesses in a company's legitimate business model), the documents discussed in the *New York Times* articles appear to contain nothing that Lilly may legitimately keep secret. Lilly's only interest in keeping them secret appears to be its interest in avoiding the reputational harm that would follow from the revelation of its apparently inappropriate conduct. But the mere fact that a document may cause a company adverse reputational consequences when revealed does not render that document a "trade secret or other confidential" information.

B. Even if the Documents Did Contain "Confidential" Information, Lilly Has Not Demonstrated "Good Cause" to Keep Them Secret

Regardless of whether the documents contain trade secrets, Lilly has not demonstrated that "good cause" exists to prohibit their disclosure. In determining whether "good cause" exists, a court should:

> consider whether the order will prevent the threatened harm, whether there are less restrictive means of preventing the threatened harm, the interests of the party opposing the motion, and *the interests of the public*. In the context of a motion to prevent dissemination of information obtained through discovery, it is appropriate to consider the other party's First Amendment interests, the nature of the information, and *whether the public has an interest in learning of that information*.

Koster v. Chase Manhattan Bank, 93 F.R.D. 471, 479-483 (S.D. N.Y. 1982) (emphasis added), citing *United States v. Hooker Chemicals & Plastics Corp.*, 90 F.R.D. 421, 425 (W.D. N.Y.1981). Here, the public has an exceptionally strong interest in the contents of the Zyprexa documents, and Lilly has demonstrated no countervailing interest sufficiently strong to justify keeping them secret.

1. Disclosure of the Documents is in the Public Interest

The existence of a strong public interest in disclosure weighs heavily against a finding of "good cause." *See, e.g.*, *Agent Orange*, 821 F.2d at 146 ("Moreover, we note that access [to discovery materials] is particularly appropriate when the subject matter of the litigation is of especial public interest, which certainly is true of the Agent Orange litigation").[5] *See also Chicago Council of Lawyers v. Bauer*, 522 F.2d 242, 258 (7th Cir. 1975) ("[M]any important social issues become entangled to some degree in civil litigation. . . . [Litigation] often exposes the need for governmental action or correction. Such revelations should not be kept from the public."), *cert. denied*, 427 U.S. 912 (1976)). The public interest in disclosure is particularly high where, as here, health and

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[5] *Agent Orange* addressed a motion to modify a pre-existing protective order. In *that context*, the Second Circuit has held that subsequent amendments to the Federal Rules of Civil Procedure have superseded *Agent Orange*'s holding that Rule 5(d) created a "presumption in favor of access to *all* discovery materials." *S.E.C. v. TheStreet.Com*, 273 F.3d 222, 233 n.11 (2d Cir. 2001) (emphasis added). Because Intervenors do not seek to modify CMO-3 but instead to apply it according to its terms, the Second Circuit's holding in *TheStreet.Com* does not cast doubt on the request to unseal the documents that formed the basis for the *New York Times* articles. Indeed, even in *TheStreet.Com*, 273 F.3d at 234-235, the Second Circuit held that the district court properly unsealed the discovery documents at issue. As the court made clear in that case, a presumption against third-party access to discovery material does *not* apply unless the protective order gave the party providing discovery a reasonable expectation that the materials will always remain secret. *See id.* Here, because CMO-3 expressly provides that documents designated "Confidential" are still subject to a challenge in which the designating party will bear the burden of proving that they should be sealed under Fed. R. Civ. P. 26(c)(7), Lilly could not have reasonably relied on the assumption that the documents would remain secret without a specific order of this Court. *See Foltz v. State Farm Mut. Auto Ins. Co.*, 331 F.3d 1122, 1138 (9th Cir. 2003) ("Because State Farm obtained the blanket protective order without making a particularized showing of good cause with respect to any individual document, it could not reasonably rely on the order to hold these records under seal forever."); *cf. Agent Orange*, 821 F.2d at 148 (concluding that "the exceptionally pervasive protection granted appellants during the pretrial stages of this litigation, coupled with the fact that appellants never were required to show good cause as mandated by Rule 26(c)," justified modification of a protective order post-settlement).

safety issues are at stake. *See, e.g., Hammock v. Hoffman-LaRoche, Inc.*, 662 A.2d 546, 558 (N.J. 1995) ("[I]ndependent of the interests of the parties and their attorneys in the litigation that comes before our courts, there is a profound public interest when matters of health, safety, and consumer fraud are involved. Prescription drugs involve both health and safety").

It should be apparent that the public has an exceptionally strong interest in learning the contents of Lilly's Zyprexa documents. About two million people worldwide took Zyprexa in 2005,[6] and more than 20 million people in total have taken the drug since its introduction in 1996.[7] Given the sheer number of people taking the drug, there is a strong public interest in having complete information about its potential risks available to mental health professionals, researchers, government regulators, and consumers..

The relative merits and risks of Zyprexa have been the subject of intense debate. A recent large-scale, government-sponsored trial tested the efficacy and side effects of perphenazine — one of the older antipsychotic drugs — against four newer, atypical drugs including Zyprexa (generically called olanzapine). *See* http://www.nimh.nih.gov/healthinformation/catie.cfm. The study, known as the CATIE study (for Clinical Antipsychotic Trials of Intervention Effectiveness), found that perphenazine was less expensive and no less effective than the newer drugs. *See id.* It concluded that Zyprexa users "experienced substantially more weight gain and metabolic changes associated with an increased risk of diabetes than those study participants taking the other drugs," and it highlighted the need to weigh the advantages of Zyprexa against

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[6] *See* Berenson, *Lilly Said to Play Down Risk, supra.*

[7] *See Eli Lilly and Company Responds to New York Times Article of 12/17/06*, Lilly News Release, Dec. 16, 2006, attached to this Motion as Exhibit # 2.

"the increased side effects." *See* http://www.nimh.nih.gov/press/catie_release.cfm.

The CATIE study underscores the need for careful analysis of the risks and benefits of antipsychotic medications for each individual. And the documents that formed the basis for the *New York Times* articles promise to provide information that will be especially important to that analysis in the context of the ongoing debate about Zyprexa. According to those articles, the documents contain evidence of Lilly's efforts to hide information about the nature and degree of risk of serious side effects of the drug, as well as Lilly's efforts to encourage the marketing of off-label uses of the drug for people with dementia, thereby exposing additional individuals to these risks. These matters are of great importance for the millions of individuals who take Zyprexa. Because of the secrecy of these documents, however, psychiatrists, their patients, researchers, regulators, and others can do nothing to clarify these issues and determine the real nature of the risk to Zyprexa users.

In sum, the documents that formed the basis for the *New York Times* articles may add critically to an ongoing debate of tremendous public importance. To keep those documents secret would inappropriately restrict that debate and prevent a fully informed analysis by professionals and regulators of the relative risks and benefits of Zyprexa as compared to other medication options. That information is critical to ensure that individuals receive the help they need to make informed decisions about their mental health care. The public interest thus weighs heavily in favor of disclosure of these

documents for much the same reasons as this Court noted in the *Agent Orange* litigation:

> The public has an interest in learning more about the nature of the issues raised by this complex litigation involving thousands of veterans and members of their families; the plaintiffs' claim of exposure to dioxin; and the chemical companies' defense that the product was harmless, produced in accordance with government specifications during warfare. Indeed, apart from the Agent Orange litigation, dioxin has sparked much public interest and debate, as contamination has been discovered in the soil of the towns and cities around the country.

In re Agent Orange Product Liability Litigation, 104 F.R.D. 559, 572 (E.D.N.Y. 1985), *aff'd,* 821 F.2d 139, *cert. denied*, 484 U.S. 953 (1987).

2. There is No Sufficient Countervailing Interest in Maintaining the Secrecy of the Documents

To show "good cause" for keeping discovery material confidential, the designating party must prove specific facts showing that disclosure would cause actual and serious harm; conclusory statements regarding injuries are insufficient. *See Joy v. North*, 692 F.2d 880, 894 (2d Cir. 1982) (refusing protective order where designating party made only broad allegations that disclosure would injure the bank in the industry and community); *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1983) ("Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not satisfy the Rule 26(c) test."); *U.S. v. Hooker Chemicals & Plastics Corp.*, 90 F.R.D. 421, 425 (W.D. N.Y. 1981) (motion for protective order denied because "movant Hooker has alleged in a most conclusory fashion that it will suffer certain injuries"). Lilly has made no such specific showing of actual harm.

Simply showing damage to a company's reputation generally does not suffice to justify sealing discovery materials. In *Joy v. North*, *supra*, the Second Circuit made that

point clear in refusing to protect a bank's internal report that contained a candid review of its internal business operations: "The potential harm asserted by the corporate defendants is in the disclosure of poor management in the past. This is hardly a trade secret." *Joy*, 692 F. 2d at 894; *see also Cipollone*, 785 F.2d at 1121 (stating that "because release of information not intended by the writer to be for public consumption will almost always have some tendency to embarrass, an applicant for a protective order whose chief concern is embarrassment must demonstrate that the embarrassment will be particularly serious," and that "[a]s embarrassment is usually thought of as a nonmonetizable harm to individuals, it may be especially difficult for a business enterprise, whose primary measure of well-being is presumably monetizable, to argue for a protective order on this ground").

Nor does the possibility that the discovered information will be shared among litigants in different lawsuits necessarily constitute "good cause" to prevent disclosure. *See Hooker*, 90 F.R.D. at 426. ("Use of the discovery fruits disclosed in one lawsuit in connection with other litigation, and even in collaboration among plaintiffs' attorneys, comes squarely within the purposes of the Federal Rules of Civil Procedure").

Of particular importance here, a tort defendant has no legitimate interest in keeping secret documents that disclose its efforts to misrepresent facts relating to public health and safety. Thus, in *Culinary Foods, Inc. v. Raychem Corp.*, 151 F.R.D. 297, 301 (N.D. Ill. 1993), the court ruled that a protective order would not encompass any information regarding whether the defendant's products were dangerous; nor would the protective order encompass information regarding the defendant's knowledge of the dangers and efforts to conceal them. "Where products are indeed hazardous, information

concerning the dangers of the products and the corporation's lack of action to prevent the dangers or its attempt to conceal the dangers should not be subject to protection under Rule 26(c)." *Id.*; *see also*, Jack B. Weinstein, Secrecy in Civil Trials: Some Tentative Views, 9 J.L & Pol'y 53, 62 (2000) (stating that "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," because such secrecy "defeats a function of the justice system - to reveal important legal factual issues to the public").

Lilly makes the speculative assertion 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." *Eli Lilly and Company Responds*, *supra*, attached to this Motion as Exhibit # 2. But a fear of "incomplete information" is not a valid basis for keeping the documents secret in this case. As the court explained in rejecting the same argument in *Nicklasch v. JLG Industries, Inc.*, 193 F.R.D. 570, 573-574 (D. Ind. 1999), a defendant has only itself to blame if the information that enters the public domain is incomplete: "If [the defendant] fears possible misinterpretation of partial information, it can release complete information and its interpretation of the data." *Id.*

CONCLUSION

For the foregoing reasons, the proposed intervenors respectfully request that the Court grant their Motions to Intervene for the purpose of challenging the confidentiality

designation of the documents that formed the basis for the *New York Times* articles, and that the Court rule that Lilly has failed to meet its burden of proving that "good cause" exists for nondisclosure of the documents.

Date: February 7, 2007

Respectfully submitted,

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February 7, 2007

INTERVENORS' EXHIBIT # 1

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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IN RE:
ZYPREXA LITIGATION,

MDL 04 1596
United States Courthouse
Brooklyn, New York
----------x
January 17, 2007
11:00 a.m.

TRANSCRIPT OF HEARING
Before: HON. JACK B. WEINSTEIN, District Judge
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INTERVENORS' EXHIBIT #2

Printer-friendly version

Eli Lilly and Company Responds to New York Times Article of 12/17/06

December 16, 2006

INDIANAPOLIS, Dec 16, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY), in a response to a story about Zyprexa in the December 17, 2006 edition of the New York Times, adds important facts and perspectives that were not evident in the story.

Said Steven Paul, M.D., Lilly's executive vice president of science and technology, "We believe it is critical to physicians and patients that Lilly state some important and relevant facts about our lifesaving medication Zyprexa that are missing from the New York Times article:

"First, contrary to incorrect statements in the Times article, Lilly has conducted more than 23 years of research on Zyprexa. And in the last ten years that the drug has been on the market, Lilly, government bodies such as the National Institute of Mental Health, and competitors -- in numerous studies that sought to show a causal link to Zyprexa and diabetes -- have not found that Zyprexa causes diabetes.

"Second, Zyprexa was approved by the FDA in 1996 and remains on the market today. In that time, it has been used by more than 20 million people worldwide, and doctors continue to prescribe it to deal with some of the most terrible mental illnesses, such as schizophrenia and bipolar disorder. The FDA has looked at the entire body of evidence that Lilly has continued to provide over the years, and has affirmed the benefit that this medicine can give to patients when accompanied by appropriate labeling regarding benefits and risks.

"Third, from the day that Zyprexa was approved, the labeling provided to physicians identified the potentially clinically-significant weight gain that was observed in more than half of all patients treated long-term with Zyprexa, as well as the diabetes-related adverse events observed in clinical trials.

"Fourth, the Times failed to mention that these leaked documents are a tiny fraction of the more than 11 million pages of documents provided by Lilly as part of the litigation process. They do not accurately portray Lilly's conduct. As part of Lilly's commitment to patients and healthcare professionals, many high-level Lilly physicians and researchers -- along with researchers from outside Lilly -- were engaged for a number of years to study the issue of Zyprexa and diabetes. Leaked documents involving these discussions do not represent an accurate view of company strategy.

"And, finally, Lilly deplores the illegal release of select confidential documents. Our concern is that this illegal and selective disclosure of incomplete information will cause unwarranted concern among patients that may cause them to stop taking their medication without consulting a physician. This is the unfortunate result we saw when plaintiffs' lawyers aggressively advertised about Zyprexa in recent years while searching for clients."

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers -- through medicines and information -- for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

Corporate News C-LLY

Zyprexa® (olanzapine, Lilly)

(Logo: http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO)

SOURCE Eli Lilly and Company

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http://www.lilly.com

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----------x

IN RE: ZYPREXA PRODUCTS LIABILITY LITIGATION

04-MDL-1596 (JBW)

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CERTIFICATE OF SERVICE

I, Andrew S. Penn, hereby certify that the following motions:

- *Pro Hac Vice* Motions of Samuel Bagenstos, Ira Burnim, Jennifer Mathis, and Andrew Penn, and supporting Notices, affidavits, certificates, and proposed Orders

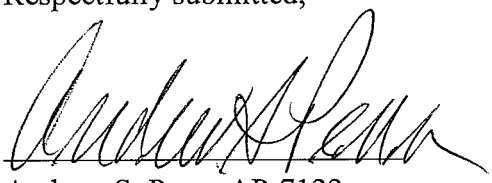
- Motions of the U.S. Psychiatric Rehabilitation Association, Mental Health America, Consumers Union, Former Mental Health Commissioners, and Individual Mental Health Professionals to Intervene and to Contest Confidentiality Designations and Memorandum of Law in Support Thereof, supporting Notice, and exhibits

were filed with the Clerk of the Court and served in accordance with the Federal Rules of Civil Procedure and/or the Eastern District's Local Rules, and/or the Eastern District's Rules on Electronic Service upon the following parties and participants:

- Nina Gussack
- Samuel J. Abate, Jr.
- Alan C. Milstein
- D. John McKay
- Ted Chabasinksi

- Alex Reinbert
- Melvyn Weiss
- Fred von Lohmann

Respectfully submitted,



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Date: February 7, 2007