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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

IN RE: ZYPREXA PRODUCTS LIABILITY LITIGATION	NO. 04-MDL-1596 MEMORANDUM OF POINTS AND AUTHORITIES OF RESPONDENTS MINDFREEDOM INTERNATIONAL, JUDI CHAMBERLIN AND ROBERT WHITAKER IN SUPPORT OF MOTION TO MODIFY CMO-3

THE COURT HAS THE POWER TO RELEASE THESE DOCUMENTS IN THE PUBLIC INTEREST

As the Second Circuit recognized in *In re Agent Orange Product Liability Litigation*, 821 F. 2d 139 (2d Cir. 1987):

> It is undisputed that a district court retains the power to modify or lift protective orders that it has entered. [Citations omitted] ...[Rules 26(c)and 5(d)]...require that discovery is presumptively open to public scrutiny unless a valid protective order directs otherwise...A plain reading of the language of Rule 26(c) demonstrates that the party seeking a protective order has the burden of showing that good cause exists for issuance of that order. It is equally apparent that the obverse is also true, i. e., if good cause is not shown the discovery materials in question should not receive judicial protection and therefore would be open to the public for inspection.

Agent Orange at 145. The court went on to point out that Rule 5(d) requires that all discovery materials must be filed with the district court unless the court orders otherwise, and reviewed the legislative history of this rule, which showed that the drafters intended the rule to be more than a housekeeping issue. The court held that this rule creates a strong presumption of the right of public access to discovery documents:

> A judge would not be expected to excuse parties from filing materials in any case in which the public or the press has an interest, such as a Watergate or similar scandal. Moreover, should the public importance of the material not appear until after filing has been excused, it is expected that the judge, upon motion of the press or other interested persons, would order the parties to file the documents for inspection...Access is particularly appropriate when the subject matter of the litigation is of especial public interest...There is no question that a Rule 26(c) protective order is subject to modification. Whether to lift or modify a protective order is a decision committed to the sound discretion of the trial court.

Agent Orange at 146-147. Respondents wish to point out here that as far as they can determine from examining the docket sheets in the underlying case, encompassing about a thousand documents filed with the court, there never was a hearing to establish whether good cause existed for granting the protective order. Rather, it seems to have been issued following a joint application of plaintiffs and defendant in the underlying mass litigation. Furthermore, the sworn testimony of Richard Meadow, a member of the plaintiffs' committee in the underlying case, during the hearing of January 17, was that defendant, of the literally millions of pages of documents it has produced in the underlying litigation here, designated virtually all of them as confidential. Transcript of January 17 hearing, 213:18 et seq. 214:17 et seq.

Balanced against defendant's complete lack of a legitimate privacy interest in the documents in question, respondents will demonstrate why a great public interest would be served in releasing the documents from the protection of CMO-3.

THE COURTS SHOULD RECOGNIZE THAT GRANTING SECRECY TO WRONGDOERS DAMAGES THE LARGER SOCIETY

The documents that defendant claims should be secret show this: certain executives of defendant corporation, motivated by greed, deliberately engaged in a course of action that they knew would cause, and did cause, the injury and death of thousands of people. Because of defendant executives' depraved disregard for human life, thousands upon thousands of innocent people were left with their bodies bloated, their health ruined, and their lives severely shortened or rapidly ended. These are serious crimes, including homicide.

Those involved in the legal system who could take action to prevent this kind of criminal behavior are often reluctant to recognize it for what it is. Two or three decades ago, the public was outraged when it was revealed that Ford executives had made the decision to maximize profit by designing a gas tank for the Ford Pinto that they knew would lead to deaths, but would be cheaper and thus more profitable to make. *Grimshaw v. Ford Motor Company*, 119 Cal. App. 3d 757 (1981). But now, this sort of behavior, especially in the drug industry, has become so common that a kind of moral numbness seems to have set in, as enormous crimes have become almost routine practices.

And it is now the legal system, rather than other government agencies like the FDA, that is most effective and necessary in bringing to

the public's attention the problems with drugs, as the FDA often acts to support the drug companies rather than protect the public. In a very recent article, even the Journal of the American Medical Association, certainly not a radical publication, has recognized that the FDA is inadequate for the task and that litigation is essential in finding the true facts about over-hyped medications. Aaron Kesselheim and Jerry Avorn, The Role of Litigation in Defining Drug Risks, *J.A.M.A.,* January 17, 2007.

THE TORT SYSTEM, FACED WITH DEFENDANTS OF ENORMOUS WEALTH AND POWER, NO LONGER IS ADEQUATE TO PREVENT THESE ABUSES

Defendant drug company has annual revenues greater than the gross national product of many small countries. Sales of Zyprexa were $4.4 billion in 2005, and $4.2 billion in 2006. The company has received over $30 billion from sales of this drug since it first came on the market in 1996. 20 million people have been given Zyprexa, often involuntarily, since its introduction. New York Times, January 20, 2007.

Theoretically, the tort system is supposed to serve the function of discouraging or preventing non-criminal but reprehensible behavior. But faced with tortfeasors for whom billion-dollar settlements are simply a cost of doing business, money damages can no longer serve this function. The only way to change this situation is through an informed public opinion and the involvement of the criminal justice system.

Yet routinely, corporate defendants are allowed by the courts to hide their behavior from the public, often with no other showing of "good cause" than that both defendants and plaintiffs have agreed that a protective order should be issued. While this may often be necessary if litigation is to be settled expeditiously, it is mistaken to think that this is somehow efficient. For after one case, or thousands of cases, are settled

with all discovery documents sealed, this secrecy means the courts soon will have to deal with a new round of lawsuits, by plaintiffs who would not have been injured but for the secrecy allowed in the earlier cases.

And of course, there is a much stronger moral imperative for the courts than the efficient settlement of cases: protecting the public.

DEFENDANT CORPORATION HAS A LONG HISTORY OF DISHONESTY IN PROMOTING ITS PRODUCTS

Eli Lilly has a long history of hiding the dangerousness of its products. In 1980, Lilly began marketing Oraflex, a drug for arthritis, in the United Kingdom and eight other countries. In 1982, it obtained FDA approval to market it in the United States. But the company hid from the FDA that Oraflex had caused many deaths and illnesses in the earlier markets. In the U.S., the company failed to warn consumers that the drug might damage the liver and kidneys. At least 100 people died from Oraflex in the U.S. The drug was withdrawn from the U.S. market in 1982, the same year it was introduced.

In 1985, Lilly was prosecuted for its handling of the drug's marketing. But although career Justice Department prosecutors believed they had strong criminal cases against several Lilly executives, they were overruled by their superiors. Lilly, the corporation, was allowed to plead guilty to a misdemeanor, and fined $25,000.

One congressman, John Conyers, commented at the time, "On the one hand, street criminals are prosecuted to the full extent of the law. On the other hand, corporate officials who may be responsible for the death and injury of hundreds of thousands of people are merely slapped on the wrist." New York Times, August 29, 1985; TIME magazine, September 2, 1985.

On September 14, 1989, after taking another best-selling Lilly drug, Prozac, Joseph Wesbecker shot eight co-workers dead and wounded twelve others before turning his gun on himself. In 1994, a wrongful death trial began in Kentucky over this incident. A verdict for the plaintiffs would have created extremely bad public relations for Lilly's blockbuster drug.

The plaintiffs convinced the trial judge to let them introduce evidence about Lilly's earlier dishonest handling of Oraflex. But as the trial proceeded, the judge noted that the plaintiffs failed to use the Oraflex evidence, and in fact did not seem to be putting on much of a case at all. Suspecting something was wrong, the judge questioned attorneys for both sides in chambers, trying to ascertain whether some secret settlement had been reached. Both sides denied it, and the case went to the jury, who promptly rendered a verdict for the defendant. Lilly then issued a press release, claiming that the verdict showed that a jury had found that Prozac was safe and effective.

But the trial judge, sensing that something was very wrong, took the extremely unusual step of "appealing" the verdict in his own court. With the approval of the Kentucky Supreme Court, the verdict was ultimately recorded as a settlement. Yet in spite of the fact that Lilly had committed a fraud on the court, no sanctions were imposed.

In 1995, in an unrelated divorce case, one of the Wesbecker plaintiffs was compelled to reveal his income, and it came out that Lilly had purchased the silence of the plaintiffs with millions of dollars. Journal of the American Bar Association, August 1996, 18: *Potter v. Eli Lilly & Co.*, 926 S.W. 2d 449 (Ky. 1996). *Winkler v. Eli Lilly*, 101 F. 3d 1196 (7th Cir. 1996)

Furthermore, in its obsession with secrecy, Lilly obtained an injunction against subsequent plaintiffs in yet another consolidated case seeking compensation for the effects of Prozac on their family members,

forbidding them from even attempting to find out the facts about the secret settlement in the earlier case. The injunction was later vacated by the 7th Circuit. *Winkler v. Eli Lilly & Co*, op. cit.

In 1997, Eli Lilly began marketing Evista, approved by the FDA for treating osteoporosis in post-menopausal women. But sales were disappointing, and so Lilly, based on very little evidence, began promoting the drug as an agent for preventing breast cancer, although the FDA had resisted giving Lilly an indication for marketing the drug for this purpose, and had even sent Lilly a warning letter about its promotional materials that made the breast cancer claim. Zeneca (now known as AstraZeneca), a Lilly competitor, at that time had the only drug on the market, Nolvadex (tamoxifen), approved to reduce the risk of breast cancer. Perceiving that Lilly's promotion of Evista for an off-label use was damaging its business interests, Zeneca sued Eli Lilly in federal court, seeking to have Lilly enjoined from wrongfully promoting Evista for a purpose for which it was not approved. The district court agreed with Zeneca, and enjoined Lilly from claiming to doctors that Evista prevented breast cancer or was superior to Nolvadex in preventing breast cancer. The court also made a finding of fact that, by making false statements about the effectiveness of Evista regarding breast cancer prevention, Lilly had created a grave public health risk. *Zeneca v. Eli Lilly & Co.,* 1999 U.S. Dist. Lexis 10852 (S.D.N.Y. 1999).

On October 24, 2002, the Cancer Prevention Coalition issued a press release warning that women taking Evista were at increased risk for ovarian cancer. Samuel Epstein, M.D., the chair of the Coalition, pointed out that Eli Lilly's own studies showed that Evista induced ovarian cancer in rats, and, at doses well below the therapeutic level, in mice. Lilly's own report of its study said, "The clinical relevance of these tumor findings is

not known." But according to Dr. Epstein, "[T]his conclusion violates the strong scientific consensus that the induction of cancer in well-designed studies in two species creates the strong presumption of human risk."

However, Eli Lilly failed to disclose this critical information in the: "Warning" section of the Physician's Desk Reference; a December 4, 1997 publication in the New England Journal of Medicine; full page advertisements in major national newspapers; and the drug's label.

Dr. Epstein also cited a 2001 study at the University of Southern California that found Evista increases the growth rate of ovarian cancer cells in laboratory studies, and thus may increase the risk of recurrence of ovarian cancer. The statement went on to criticize the National Cancer Institute's "continuing silence on this avoidable risk of ovarian cancer despite its annual multibillion-dollar taxpayers' funding."

In 2002, the U.S. Department of Justice notified Lilly that it was initiating a criminal investigation into Lilly's marketing of Evista. In a later criminal filing against the company, the DOJ said that Lilly's illegal marketing of Evista continued from 1998 to as late as 2000, in spite of the 1999 injunction. On December 21, 2005, the DOJ announced in a press release that Lilly (the corporation, not any of its executives) "agreed to plead guilty and to pay $36 million in connection with its illegal promotion of Evista." It also entered into a consent decree for a permanent injunction.

On the same day the DOJ announced its action, Don Woodley, a principal with Woodley Ferra Manion Portfolio Management, was quoted in the Washington Post as saying, "This settlement is very reasonable and affordable. It's chump change for a company of Lilly's size." By that time, global sales of Evista had reached $770.8 million for the first nine months of that year.

It is not known how many women may have been injured or killed as a result of Lilly's illegal marketing of Evista. However, it is known that sales of Evista in its first year on the market were about $120 million, and in 2003 were $922.1 million. Bloomberg News, March 26, 2004; DOJ press release, December 21, 2005.

And of course the documents in question here show that defendant, over a number of years, misled doctors and the public about the true effects of Zyprexa, either by false statements or by suppressing the facts.

THE VICTIMS OF DEFENDANT'S WRONGDOING ARE AMONG THE MOST VULNERABLE AND POWERLESS GROUPS IN OUR SOCIETY, AND MOST IN NEED OF THE PROTECTION OF THE COURTS

Zyprexa is a drug of the class known as "antipsychotics." As such, it is generally administered to people who have received a psychiatric diagnosis of schizophrenia or bipolar disorder, although defendants have been illegally promoting the drug for other conditions as well. And people who have been given this label are among the most powerless and disrespected groups in America. As Judi Chamberlin writes in her book *On our Own: Patient-Controlled Alternatives to the Mental Health System* (McGraw-Hill, 1979):

> *Mental health* and *mental illness* are terms that have entered the popular vocabulary. Yet they are terms that few people can define. Lay people and psychiatrists alike tend to call people mentally healthy when they like their behavior and mentally ill when they dislike their behavior. Rebellious teenagers, unhappy housewives, dissatisfied workers, or lonely old people, for example, are often diagnosed as mentally ill, which is less a medical, scientific description than it is a judgment that the person so labeled has, in some way, behaved improperly.
>
> We can see this judgmental process at work when we look at the effect that a diagnosis of mental illness has on an

> individual's life. Unlike physical illnesses, which affect particular parts of a person's body, mental illness affects that abstraction known as the mind. Once it has been decided that a person has a sick mind, enormous social consequences ensue. A finding of mental illness, which is often a judicial, as well as a medical, determination, frequently results in loss of liberty. People labeled mentally ill are usually presumed to be incapable of exercising their decision-making power in their own best interest. The compulsory psychiatric treatment of people labeled mentally ill usually involves confinement in a mental hospital, which is widely [and correctly] perceived as an unpleasant and undesirable fate. Mental patients who protest such confinement are seen as being unable to understand their own best interest; and often, once someone has been so diagnosed, even the perception of his or her place of confinement as undesirable or unpleasant is considered a sign of mental illness.

One young woman quoted in Chamberlin's book describes poignantly the reactions of those who knew her before her hospitalization, and her own self-doubt and destroyed self-esteem:

> For a long time after I got out, I stayed home all the time, except when I was at school. I stopped going to feminist meetings, although I had been very active before. Women in the women's movement...women I had known for a long time and worked with, started treating me differently after I had been in the hospital. They were oppressing me. They wouldn't tell me things, wouldn't ask me to do any work, because they thought I couldn't handle stuff. They had been my friends, but now they would look at me as if I was crazy. When I tried to talk about it, I was afraid I was being paranoid.

Once out of the institution, former psychiatric patients, if others know their history, face constant reminders of their inferior status. Before the Americans with Disabilities Act, job applications routinely included a question about whether the applicant had ever been hospitalized for mental illness. Newspaper headlines, which not too long ago often read "Negroes Rob Bank in Broad Daylight," now frequently say something like

"Mental Patient Assaults Woman on Main Street." Of course, one never reads "Normal Person Commits Crime."

And the popular culture and vocabulary reinforce this, with phrases like "nut case" frequently used in ordinary conversation.

Although tens of millions of people have spent time as inpatients in psychiatric wards (according to the National Institute of Mental Health in 1982), the overwhelming majority of people with such a history hide it, for obvious reasons. Thus, although one may be literally surrounded by people with psychiatric histories, the general impression is that only a tiny group of people have been psychiatric inpatients.

Thomas Szasz, a psychiatrist and well-known critic of his own profession, has said:

> "Schizophrenia" is a strategic label, like "Jew" was in Nazi Germany. If you want to exclude people from the social order you must justify this to others but especially to yourself. So you invent a justificatory rhetoric. That's what the really nasty psychiatric words are all about: they are justificatory rhetoric, legitimizing the removal of the people so labeled from society. It's like labeling a package "garbage"; it means, "take it away," "get it out of my sight," etc. That's what the word "Jew" meant in Nazi Germany; it did not mean a person with a certain kind of religious belief. It meant "vermin," "gas him!" I am afraid that "schizophrenia" and "sociopathic personality" and many other psychiatric diagnostic terms mean exactly the same thing.

"Interview: Thomas S. Szasz, MD," *The New Physician,* June 1969.

And it is little-known, but very important to know, that psychiatric patients in Nazi Germany, long before the Holocaust reached the full depth of its horrors, were the first group to be slaughtered in the gas chambers. Frederick Wertham, A Sign for Cain: An Exploration of Human Violence, Paperback Library, New York, 1969.

In a recent review of a book on medical experimentation on African-Americans, the New York Times wrote, in words that apply equally well to the position of psychiatric patients:

> ...[P]eople in power have always been capable of exploiting those they regard as "other," and of finding ways to rationalize the most atrocious abuse. The victims are declared defective, violent...or a drain on the community. The medical tinkering is for their own good, and the greater good of society."

New York Times, January 23, 2007, review of Harriet Washington, Medical Apartheid, Doubleday, 2007.

In the last few decades, the American legal system has begun to recognize that psychiatric patients should be protected from arbitrary deprivation of their liberty. *O'Connor v. Donaldson*, 422 U.S. 563 (1975); California Welfare and Institutions Code, section 5000 et seq. And the courts have started to acknowledge the seriousness of forcing powerful psychiatric drugs on people without their consent. *Rogers v. Commissioner of Mental Health*, 390 Mass. 489, 458 NE 2d 308 (1983); *Riese v. St. Mary's Hospital*, 259 Cal. Rptr. 669, 774 P 2d 698 (1989); *Myers v. Alaska Psychiatric Institute*, 138 P. 3d 238 (2006). But in practice, such legal protections are often not enforced, particularly in the area of forced drugging. California and Massachusetts, where some of the most important and earliest cases on the right to refuse psychiatric drugs were decided, have set up programs of quasi-judicial hearings to enforce the courts' holdings. But advocates from those states report that patients rarely win such hearings. This means that for most institutionalized psychiatric patients, there is no choice whether to take such toxic drugs as Zyprexa. More is needed to protect these people than some words on a package insert that they will never see.

One protection could be an aroused public opinion. Another is the necessity of criminal prosecutions of those drug company leaders who promote their products by lying about and hiding the true effects of these drugs. But if the courts allow drug companies to keep their criminal activities secret, it makes it much more difficult to protect their victims.

Psychiatric patients are not nut cases, schizophrenics, or "lives unworthy of life." We are human beings, deserving of the same respect as all other persons. And we are citizens, who are entitled to the equal protection of the law. If the words of the Declaration of Independence and the Fourteenth Amendment have any real meaning, the law should protect, not the desire for secrecy of the defendant, but the welfare and the very lives of the defendant's victims.

THE COURT SHOULD NOT BE COMPLICIT IN PROTECTING DEFENDANT FROM THE JUST CONSEQUENCES OF ITS BEHAVIOR

All human life is sacred. Societies that have lost sight of this moral imperative have become nations of lynch mobs and gas chambers. The documents that defendant corporation wants to keep secret show that its executives have violated, and continue to violate, this basic premise that holds decent societies together. Respondents urge this court to refuse to keep secret the evidence that would show the public that the officials of Eli Lilly are culpable, not of negligence or overly-sharp business practices, but of crimes against humanity.

Respectfully submitted,

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