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7
8 UNITED STATES DISTRICT COURT
9 EASTERN DISTRICT OF NEW YORK

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

17 **THE COURT HAS THE POWER TO RELEASE**
18 **THESE DOCUMENTS IN THE PUBLIC INTEREST**

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

21 It is undisputed that a district court retains the power to
22 modify or lift protective orders that it has entered. [Citations
23 omitted] ...[Rules 26(c) and 5(d)]...require that discovery is
24 presumptively open to public scrutiny unless a valid protective
25 order directs otherwise...A plain reading of the language of Rule
26 26(c) demonstrates that the party seeking a protective order
27 has the burden of showing that good cause exists for issuance
28 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.

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

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

19
20 *Agent Orange* at 146-147. Respondents wish to point out here that as far
21 as they can determine from examining the docket sheets in the underlying
22 case, encompassing about a thousand documents filed with the court,
23 there never was a hearing to establish whether good cause existed for
24 granting the protective order. Rather, it seems to have been issued
25 following a joint application of plaintiffs and defendant in the underlying
26 mass litigation. Furthermore, the sworn testimony of Richard Meadow, a
27 member of the plaintiffs' committee in the underlying case, during the
28 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.

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

5
6 **THE COURTS SHOULD RECOGNIZE THAT GRANTING**
7 **SECRECY TO WRONGDOERS DAMAGES THE LARGER SOCIETY**

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

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

26 And it is now the legal system, rather than other government
27 agencies like the FDA, that is most effective and necessary in bringing to
28

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

8
9 **THE TORT SYSTEM, FACED WITH DEFENDANTS**
10 **OF ENORMOUS WEALTH AND POWER, NO LONGER**
11 **IS ADEQUATE TO PREVENT THESE ABUSES**

12 Defendant drug company has annual revenues greater than the
13 gross national product of many small countries. Sales of Zyprexa were
14 \$4.4 billion in 2005, and \$4.2 billion in 2006. The company has received
15 over \$30 billion from sales of this drug since it first came on the market in
16 1996. 20 million people have been given Zyprexa, often involuntarily, since
its introduction. *New York Times*, January 20, 2007.

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

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

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

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

6
7 **DEFENDANT CORPORATION HAS A LONG
8 HISTORY OF DISHONESTY IN PROMOTING ITS PRODUCTS**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

28

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

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

10

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

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

22 *Mental health and mental illness* are terms that have entered
23 the popular vocabulary. Yet they are terms that few people can
24 define. Lay people and psychiatrists alike tend to call people
25 mentally healthy when they like their behavior and mentally ill
26 when they dislike their behavior. Rebellious teenagers,
27 unhappy housewives, dissatisfied workers, or lonely old people,
28 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

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

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

21 For a long time after I got out, I stayed home all the time,
22 except when I was at school. I stopped going to feminist
23 meetings, although I had been very active before. Women in
24 the women's movement...women I had known for a long time
25 and worked with, started treating me differently after I had
26 been in the hospital. They were oppressing me. They wouldn't
27 tell me things, wouldn't ask me to do any work, because they
28 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

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

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

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

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

13
14 "Schizophrenia" is a strategic label, like "Jew" was in Nazi
15 Germany. If you want to exclude people from the social order
16 you must justify this to others but especially to yourself. So you
17 invent a justificatory rhetoric. That's what the really nasty
18 psychiatric words are all about: they are justificatory rhetoric,
19 legitimizing the removal of the people so labeled from society.
20 It's like labeling a package "garbage"; it means, "take it away,"
21 "get it out of my sight," etc. That's what the word "Jew" meant
22 in Nazi Germany; it did not mean a person with a certain kind of
23 religious belief. It meant "vermin," "gas him!" I am afraid that
24 "schizophrenia" and "sociopathic personality" and many other
25 psychiatric diagnostic terms mean exactly the same thing.

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

27 And it is little-known, but very important to know, that
28 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.

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

4
5 ...[P]eople in power have always been capable of exploiting
6 those they regard as "other," and of finding ways to rationalize
7 the most atrocious abuse. The victims are declared defective,
8 violent...or a drain on the community. The medical tinkering is
9 for their own good, and the greater good of society."

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

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

