Fred von Lohmann (FV 3955)

Appearing pro hac vice

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UNITED STATES DISTRICT CO	OURT
EASTERN DISTRICT OF NEW	YORK

In re: ZYPREXA LITIGATION

No. 07-CV-0504 (JBW)

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

### **EXHIBIT E**

1	UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK		
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3		X :	
4	IN RE: ZYPREXA PRODUCTS	: : U.S. Courthouse	
5	LIABILITY LITIGATION	N : Brooklyn, New York :	
6		: TRANSCRIPT OF PROCEEDINGS : January 8, 2007	
7		X 2:00 p.m.	
8	BEFORE:		
9	HONORABLE JACK E	3. WEINSTEIN, U.S.D.J.	
10		,	
11	APPEARANCES:		
12	Eli Lilly & Co.	- SEAN P. FAHEY, ESQ. NINA GUSSACK, ESQ.	
13 14	Mind Freedom International, - TED CHABASINSKI, ESQ. Chamberlin, Whittiker		
15	EFF, John Doe	- FRED VON LOHMANN, ESQ.	
16	AHRP, Vera Sharav	- ALAN MILSTEIN, ESQ.	
17	Gottsteins	- JOHN McKAY, ESQ.	
18	Steering Committee	- RICHARD MEADOW, ESQ.	
19	Third-party claims	- TOM SOBOL, ESQ.	
20	Count Department	W. 1	
21	Court Reporter:	Mickey Brymer, RPR Official Court Reporter	
22		225 Cadman Plaza East Brooklyn, New York 11201 (718) 613-2255	
23		(. 10) 013-5533	
24	Decondina	In made 2 1 1	
25		by mechanical stenography.	

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1 THE CLERK: Civil cause for reargument of motion in

- 2 re Zyprexa Products Liability Litigation.
- 3 The Judge is on the bench now.
- 4 THE COURT: I'll ask for appearances, please.
- 5 THE CLERK: Counsel, restate your names, please.
- 6 MR. CHABASINSKI: Ted Chabasinski representing Mind
- 7 Freedom International, Chamberlin and as of yesterday Robert
- 8 Whittiker.
- 9 MR. VON LOHMANN: Fred Von Lohmann, Electronic
- 10 Frontier Foundation, representing John Doe.
- 11 MR. MILSTEIN: Alan Milstein, representing Vera
- 12 Sharav and the Alliance for Human Research Protection.
- 13 THE COURT: Anyone else?
- 14 MS. GUSSACK: Nina Gussack for defendant Eli Lilly
- 15 and Company.
- MR. McKAY: John McKay for Harry Gottstein,
- 17 respondent for the second temporary restraining order and
- 18 James Gottstein pursuant to the --
- 19 THE COURT: Keep your voices up, please. This is the
- 20 Judge speaking. When you speak, give your name. I'll have
- 21 the people who are present give your names, please.
- 22 MR. FAHEY: Sean Fahey on behalf of Eli Lilly and
- 23 Company.
- MR. AVELAR: I'm not entering an appearance, your
- 25 Honor, I'm not admitted to practice.

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1 MR. MEADOW: Richard Meadow, Lanier law firm,

- 2 plaintiffs, and a member of the plaintiff's steering
- 3 committee.
- 4 THE COURT: Your name.
- 5 MR. AVELAR: My name --
- 6 THE COURT: Keep your voice up, sir. My name is Paul
- 7 Avelar, but I'm not admitted to practice before the Court and
- 8 I will not be speaking at the hearing.
- 9 THE COURT: Who do you represent?
- 10 MR. AVELAR: I'm here with Mr. Fahey.
- 11 THE COURT: You are an associate?
- 12 UNIDENTIFIED SPEAKER: Your Honor, I'm sorry, I can't
- 13 hear the conversation.
- 14 THE COURT: Keep your voice up. Sir, say it again.
- 15 If you're studying to be a lawyer, speak up.
- MR. AVELAR: My name is Paul Avelar. I am an
- 17 associate of Mr. Fahey. I will not be entering an appearance
- 18 in this case. I am not admitted to practice before this
- 19 Court.
- 20 THE COURT: Thank you.
- MR. SOBOL: One more on the phone, your Honor. Good
- 22 afternoon, your Honor. This is Tom Sobol, S-o-b-o-l, I'm one
- 23 of the co-lead lawyers for the third-party claims. Good
- 24 afternoon.
- THE COURT: Good afternoon.

- 1 Who wishes to speak first? Is there an application?
- MR. CHABASINSKI: There is a motion for reargument.
- 3 This was originally called because I requested wording in the
- 4 injunction be changed.
- 5 THE COURT: Give your name.
- 6 MR. CHABASINSKI: I did, your Honor. This is Ted
- 7 Chabasinski representing, among other respondents to the
- 8 injunction, Mind Freedom International. Originally I wrote to
- 9 you and requested that the wording in the injunction as
- 10 applied to my client be changed because I felt it was --  ${ t I}$
- 11 felt it was restraining their free speech beyond what the
- 12 injunction could call for. I think the situation is
- 13 completely changed now and I think it would be more
- 14 appropriate for you to hear Mr. Von Lohmann's argument.
- 15 Although he's only representing one person in the injunction,
- 16 his arguments really apply to everyone who's covered by the
- 17 injunction. So, I request that you hear his arguments first.
- 18 They would make my argument moot.
- 19 THE COURT: I will be happy to hear him.
- 20 MR. VON LOHMANN: Your Honor, this is Fred
- 21 Von Lohmann, representing John Doe, and I am happy to restate
- 22 the arguments that were made in the brief that was filed very
- 23 early this morning. I apologize if you have not had a chance
- 24 to take a look at that.
- 25 THE COURT: I read all the papers.

- 1 MR. VON LOHMANN: Excellent, your Honor. Thank you
- 2 very much. I appreciate that. Let me recap briefly a few
- 3 things before I discuss the argument. First, in response to
- 4 the papers filed by Eli Lilly attorney Ms. Gussack, let me
- 5 make a few things clear. First, my client John Doe is not
- 6 anyone named in the injunction, nor anyone mentioned by name
- 7 in Ms. Gussack's papers. Just so we're clear, my client here
- 8 is someone who is a member of the public who is interested in
- 9 mental health issues, who has heard about this, thanks to The
- 10 New York Times article as well as the broad public discussion
- 11 about this and is not someone who is enlisted as one of the
- 12 individuals in the Court's prior injunction.
- 13 Second, your Honor, unlike the assertion in
- 14 Ms. Gussack's papers, I certainly do not concede personal
- 15 jurisdiction over my client has been established by the
- 16 Court. I agree that my client is potentially within this
- 17 Court's jurisdiction. However, he has not been served, nor
- 18 otherwise formally brought under this Court's jurisdiction. I
- 19 appear here today because the case law is relatively clear
- 20 that someone who has notice of a Court injunction will be
- 21 bound by that injunction even without formal service, so, I
- 22 appear here today in order to clarify the Court's order in
- 23 that regard.
- 24 Third, my client also does not concede that due
- 25 process has been fulfilled with respect to his situation.

- 1 This again is something that was asserted by Ms. Gussack's
- 2 papers filed before the Court this morning. He was not
- 3 notified in any way prior to the issuance of the court order.
- 4 So, let me just recap briefly the arguments here that
- 5 he is seeking to make and answer any questions the Court may
- 6 have. He is someone who contributes to the web site that is
- 7 mentioned in the Court's January 4 order, the
- 8 Zyprexa.pbwiki.com web site. He has, in addition to
- 9 contributing information there, he has also posted links to
- 10 the Lilly documents that are hosted on third-party web sites.
- 11 He himself has never posted the documents. He has only posted
- 12 links that purportedly lead to these documents.
- 13 As the Court may be aware, there are now a number of
- 14 locations on the Internet where the documents have apparently
- 15 been republished and again I would like to disagree with
- 16 Ms. Guzack's papers. She asserts that the documents are
- 17 nowhere available on the Internet currently. I certainly have
- 18 no information confirming that. In fact, what I am aware of
- 19 is that the documents may in fact already be available on
- 20 foreign web sites. Of course, my client is leery of
- 21 publishing links to those web sites in light of the Court's
- 22 order, but my understanding is the documents are presently
- 23 available on third-party web sites with no relation, at least
- 24 no relation that my client knows to any party in the case or
- 25 any person named in the injunction.

- 2 arguments in asking the Court to clarify its order to exclude
- 3 him and his activities. First, this Court lacks the authority
- 4 to bind nonparties who are not acting in concert with or
- 5 participating with or aiding or abetting a party to the
- 6 underlying action. And, as described in my brief, my client
- 7 certainly does not fall within that circle. He is not a party
- 8 to the litigation. He has never taken this drug, he has to
- 9 the best of his knowledge never had any direct contact with
- 10 any individual who is bound by this Court's protective order
- 11 CMO-3.
- 12 He discovered this controversy, as I said, through
- 13 public sources of information and accordingly he is not in a
- 14 position of aiding or abetting or otherwise participating with
- 15 any party. Therefore, it is his view he is not within the
- 16 Court's power, even if he is in fact posting the links to
- 17 these documents.
- 18 The Court's order, however, enjoins any -- apparently
- 19 from the language as written in the January 4th order, it
- 20 appears to enjoin the web site itself and my client therefore
- 21 is concerned that that would include his activities, despite
- 22 the fact that he is an independent third party and thus beyond
- 23 the Court's reach.
- Secondly, and perhaps even more importantly, my
- 25 client believes that this order as applied to his activities

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1 constitutes an unconstitutional prior restraint on speech and

- 2 in this regard, as discussed in the brief, the Proctor &
- 3 Gamble versus Bankers Trust case, the 6th Circuit case from
- 4 1996 that -- where Judge Merritt wrote the majority opinion
- 5 there is really almost exactly on all fours with this
- 6 circumstance.
- 7 In that case BusinessWeek obtained documents that
- 8 were under protective order and submitted to the Court under
- 9 seal and wanted to publish an article relating to those
- 10 documents. The Court enjoined that publication. On review
- 11 the 6th Circuit made it very clear that injunction was a prior
- 12 restraint, unconstitutional, and impermissible under the First
- 13 Amendment.
- 14 The circumstance here is again very similar. My
- 15 client is an independent third party that has discovered
- 16 places that purport to have these documents on line. The fact
- 17 that they were under protective order in this litigation
- 18 before your Honor should not be a justification to assert a
- 19 prior restraint against him.
- 20 In fact, although Ms. Guzack's papers suggest that
- 21 The Seattle Times versus Reinhart case before the Supreme
- 22 Court in 1984 upheld similar restrictions, that case and the
- 23 restrictions that were upheld in that case were against a
- 24 party to the litigation itself and, as Judge Merritt describes
- 25 in the Proctor & Gamble case, rejecting exactly that argument,

- $1\,$  he points out that in The Seattle Times case we were not there
- 2 talking about nonparties. My client, just as BusinessWeek was

- 3 in the Proctor & Gamble case, is here a nonparty acting
- 4 independently of any party or for that matter any person who
- 5 is under the Court's protective orders CMO-3.
- 6 So, for those two reasons, I have suggested in my
- 7 brief a revision or clarification of the Court's January 4th
- 8 order that I believe would cure both the Court authority
- 9 problem as well as the First Amendment prior restraint
- 10 problem, and that is essentially to remove mention of the web
- 11 site and specifically I think it is more sensible to direct
- 12 the Court's orders at individuals rather than a web site that
- 13 in this case can be revised by many, many members of the
- 14 public and, also, to clarify that the Court's order only
- 15 extends to nonparty -- to the extent they are legally
- 16 identified with a party, or are acting in concert with or
- 17 participate with or aiding and abetting a party, that is
- 18 clearly the outer limit of the Court's authority, as made
- 19 clear by both 2d Circuit authority and Supreme Court
- 20 authority.
- So, by clarifying the order in that manner it would
- 22 retain the Court's power over anyone who is in that close
- 23 aiding and abetting relationship, thereby validly protecting
- 24 Eli Lilly's interests while not reaching out onto a prior
- 25 restraint to nonparties who are both beyond the Court's

- 1 authority and protected by the First Amendment in their
- 2 interest in publicizing and discussing information relating to

- 3 the Lilly documents, your Honor.
- 4 THE COURT: Thank you very much. Do you have the
- 5 transcript of the hearing of January 3, 2007?
- 6 MR. VON LOHMANN: Your Honor, I only obtained that
- 7 transcript this morning as an exhibit to Ms. Gussack's
- 8 submission. I have not had the opportunity to review it.
- 9 THE COURT: But do you have a copy?
- MR. VON LOHMANN: I do, yes, your Honor.
- 11 THE COURT: Are you appearing on behalf of the web
- 12 site?
- 13 MR. VON LOHMANN: I am appearing on behalf of an
- 14 individual who has contributed to the web site, including
- 15 contributing links that lead -- at least purportedly lead to
- 16 the Lilly documents that are in dispute.
- 17 It is a bit unclear, your Honor, exactly who the
- 18 order is directed toward. As I described in my brief, the web
- 19 site is hosted by a service called pbwiki.com. That service
- 20 is based in California and it basically provides the tools
- 21 that allows anyone to create a web site on any topic of their
- 22 choosing. In fact, their information, their public
- 23 information on the web site suggests that they have more than
- 24 100,000 individual web sites that are hosted by this service.
- 25 So, by mentioning a particular web site, in this case the

- 1 Zyprexa.pbwiki.com web site, I interpret the Court's ruling to
- 2 be applied just to that individual web site rather than to the
- 3 entire operations of this company which obviously has no

- 4 direct interest or involvement in this controversy or this
- 5 underlying litigation. And, so, when you say "the web site,"
- 6 all I can say, your Honor, is that there are a number of
- 7 individuals who are contributors to that web site, each of
- 8 whom is entitled to revise the web site as they see fit. The
- 9 wiki technology involved here allows that sort of
- 10 collaborative authorship.
- 11 All I can do, your Honor, is represent one of the
- $12\,$  authors. I don't know who all the other authors are. As I
- 13 mentioned in my brief, the password that is required to be an
- 14 author or a collaborator on this web site has been publicly
- 15 disclosed so to the best of our knowledge there are a number
- 16 of individual contributors, not all of whose identities are
- 17 known to my client, or, as far as I can tell, publicly
- 18 available. So, I am here representing one individual who
- 19 contributes to this particular web site.
- 20 THE COURT: But you'll have to excuse me, because I
- 21 don't know too much about the technology involved and counsel
- 22 will have to assist me.
- MR. VON LOHMANN: I will do my best, your Honor.
- 24 THE COURT: I know you will.
- Is there a company that owns and operates the web

- 1 site?
- MR. VON LOHMANN: The company, as I mentioned,
- 3 there's a company called P.B. Wiki. It is based in

- 4 California. It owns and operates a service that hosts many,
- 5 as I mentioned, over 100,000 web sites. It has no particular
- 6 interest in the content of any particular web site, nor to the
- 7 best of my knowledge does it author any of that content. It
- 8 simply provides in essence to your Honor something similar to
- 9 a generic bulletin board where anyone can come and pin up any
- 10 content they like and they -- although I haven't been in touch
- 11 with that company, to my knowledge they are not involved or
- 12 appearing or otherwise represented here.
- 13 THE COURT: So, they are not objecting to the order;
- 14 is that right?
- MR. VON LOHMANN: I cannot speak on their behalf. I
- $16\,$  -- I did speak with them, because, as I mentioned in my
- 17 brief, counsel, Mr. Fahey, who I believe is on the call, today
- 18 sent an E-Mail message to the company. This actually occurred
- 19 prior to the Court's January 4th ruling, so even before the
- 20 web site was mentioned in a court order, counsel for Lilly
- 21 already contacted the company and demanded that the entire web
- $^{22}$  site be taken down or deleted and, so, I got in the touch with
- 23 the company in order to discuss this matter with the company.
- 24 The company was satisfied that because the web site, as I
- 25 mentioned in my brief, has edited itself, the contributors

- 1 have chose to abide by the Court's January 4th ruling pending
- 2 this hearing. The company was satisfied that the web site, to
- 3 the extent it was in compliance with the Court's ruling, no
- 4 longer presented any issue that they needed to worry about.

- 5 Again, your Honor, this is me relaying the content of
- 6 my conversation. I don't purport to represent them. They are
- 7 not, as far as I know, involved in this action at this time.
- 8 THE COURT: Thank you. Does anybody else wish to be
- 9 heard before I hear from Lilly?
- 10 MR. CHABASINSKI: Your Honor, this is Ted
- 11 Chabasinksi. I believe Mr. Von Lohmann's argument applies
- 12 equally to the people I represent. The injunction, it
- 13 infringes on their freedom of speech. They are in no way
- 14 party identified. The event that Lilly claims ties them to
- 15 the parties, that is, the alleged violation of the protective
- 16 order, there still hasn't been a determination there even was
- 17 a violation of protective order. The only thing that connects
- 18 people I represent to any party is that they receive some
- 19 documents -- not all of them received them. They received
- 20 some documents from somebody who is also not a party and that
- 21 their connection with this case is extremely tenuous. They
- 22 are nonparties, they have no relationship to any party. If,
- 23 indeed, they had a relationship to Mr. Gottstein,
- 24 Mr. Gottstein is not a party, there's no showing that they
- 25 acted in concert with Mr. Gottstein or aided and abetted any

- 1 alleged violation of the protective order.
- 2 So, I think all of Mr. Von Lohmann's argument as to
- 3 his client apply to mine as well.
- 4 I also -- I have not received any papers from Eli

- 5 Lilly. I don't know what they say, but whatever they say, I
- 6 don't think they change what the law is in this area, which is
- 7 prior restraint is disfavored and people have to be related to
- 8 the -- to some party in the case in some way before they can
- 9 be bound by an injunction.
- 10 THE COURT: Thank you very much. Does anybody else
- 11 on the phone wish to be heard?
- MR. MILSTEIN: Yes, your Honor, this is Alan
- 13 Milstein. I represent Vera Sharav and Alliance for Human
- 14 Research Protection. Ms. Sharav is a patient, subject
- 15 advocate who indicated to me on her web site and E-Mails
- 16 information that she sees as exposing the risks of
- 17 pharmaceuticals and of other health related matters and she is
- 18 a nonparty, as is AHRP, to the litigation, the subject
- 19 litigation and should not be bound by any kind of restraining
- 20 order. So, I would again endorse what counsel for the
- 21 Frontier Foundation has already said to your Honor.
- THE COURT: Thank you. Anybody else on the phone?
- 23 MR. McKAY: Your Honor, this is John McKay,
- 24 representing first Terry Gottstein as a respondent to the
- 25 order that is at issue in this case. I would simply -- I have

- 1 nothing further to add. It appears the brief filed by
- 2 Mr. Von Lohmann correctly states the law that is applicable
- 3 and Ms. Gottstein, under her circumstances, is not affected by
- 4 this. On behalf of Mr. Gottstein, who is not a party to this
- 5 restraining order, I would simply note for the record that we

- 6 appreciate that your Honor has provided to Mr. Gottstein an
- 7 opportunity to respond more specifically to matters that have
- 8 been raised by the pleadings till next Tuesday, January 16th,
- 9 and that we believe that a number of the statements in the
- 10 pleadings that have been filed that we've had a chance to look
- 11 at quickly this morning by Lilly do not accurately reflect
- 12 what we believe the record will ultimately show and in
- 13 particular consistent with your Honor's determination at our
- 14 last hearing on January 3rd that you were not predetermining
- 15 the factual issues. We appreciate that and the opportunity to
- 16 more fully address this next week, when we make a scheduled
- 17 filing.
- 18 Thank you, your Honor.
- 19 THE COURT: Thank you. Anybody else?
- 20 (No response.)
- 21 THE COURT: I will hear from Lilly.
- MR. FAHEY: Your Honor, I want to start by focusing
- 23 the Court's attention on why we're here. This is a motion for
- 24 reargument, which is a very high standard that must be met in
- 25 order to change a prior ruling if the Court overlooked the

- 1 controlling decision, factual matters that would have likely
- 2 changed the result, and, secondly, argument would be necessary
- 3 to correct error. Neither of those is present here. The
- 4 reason for needing the reargument stated in Mind Freedom's
- 5 letter to the Court was that the order resulting from the

- 6 January 3rd hearing was the result of a lack of due process.
- 7 That is not true either.
- 8 First of all, due process is a very low standard.
- 9 Notice and opportunity to be heard are all that is needed.
- 10 Both of those were provided to all the parties on the phone
- 11 today. Particularly in a situation as we have here, where the
- 12 proceedings are to be followed by a more extensive proceeding
- 13 which is still scheduled for January 16 on a lot of the First
- 14 Amendment issues that were raised in the call today, the due
- 15 process standard is even lower.
- There was communication or allegations in both the
- 17 moving papers and, also, on various web sites that there were
- 18 ex parte communications which resulted in an expansion of the
- 19 Court's order. As our papers show, the expansion of the order
- 20 in this case was specifically discussed on the record and the
- 21 expansion of the order was directed by the Court after
- 22 discussion with all the parties participating. Let me try to
- 23 briefly address some of the issues with respect to -- I guess
- 24 I will take them in order.
- With respect to the EFF motion, we would like to

- 1 discuss the issue of the anonymity of John Doe. We think
- 2 that's a very important issue. The allegations are that John
- 3 Doe has nothing to do with the people who are under court
- 4 order on the 29th, that he has never spoken with anyone that
- 5 had anything to do with that, but he failed to tell us who he
- 6 is. And, so, we think the cases cited by EFF in their brief

- 7 do not support the preservation of John Doe's identity. We
- 8 are more than happy to have John Doe's identity sealed in the
- 9 record, but in order for the Court to determine whether or not
- 10 he was aiding and abetting people who were under Court orders
- 11 and injunctions in this case, we need to know who he is. And,
- 12 so, that's the first thing.
- So, there's two factual points that EFF relies on in
- 14 their argument. First is that there was no aiding and
- 15 abetting, that we don't know who John Doe is. The second is
- 16 that the documents are widely available on the Internet.
- 17 There's no evidence before you, your Honor, that they are
- 18 widely available on the Internet. The only evidence is the
- 19 evidence that we submitted this morning from the director of
- 20 Mind Freedom, who said and we quoted in our brief, "I know of
- 21 no place on the Internet where these documents can be
- 22 located." So, the factual basis for EFF's motion for
- 23 reargument, first of all, doesn't make the standard for
- 24 reargument, but even on a factual basis the factual record is
- 25 not sufficient for your Honor to rule on their request to

- 1 change the order.
- The second point and I do think that regardless of
- 3 who the John Doe is the evidence of the aiding and abetting of
- 4 individuals in -- that are under court order is significant by
- 5 the members of the contractors of the pbwiki. I will go
- 6 through those in a moment.

- 7 And, so --
- 8 THE COURT: I don't want to hear the evidence in
- 9 detail. I have your papers.
- 10 MR. FAHEY: Okay. Some of this is just responding to
- 11 the brief we just got this morning to which we didn't have an
- 12 opportunity to respond.
- 13 THE COURT: I don't want to hear that detail.
- MR. FAHEY: Okay.
- 15 The next issue with respect to the EFF's argument
- 16 about the 6th Circuit case, again, this is something we would
- 17 be prepared to address on the 16th with respect to the First
- 18 Amendment issue, but the fact is that the Proctor & Gamble
- 19 case is not at all similar to this case and Proctor & Gamble
- 20 there was not a court ordered protective order, there was an
- 21 agreement reached by the parties to keep information
- 22 protected. There was no good cause showing that there is here
- 23 which allowed the Court to make a determination about whether
- 24 a protective order was necessary.
- In the Proctor & Gamble case the parties were allowed

- 1 on their own without Court approval to modify the terms of the
- 2 protective order, and, so, the government action in this case
- 3 was not present in the Proctor & Gamble case. Seattle Times
- 4 is controlling here. Seattle Times made clear that it has
- 5 been in the Court's power to issue protective orders
- 6 recognizing there's going to be some restraint of the First
- 7 Amendment rights. The Court balanced that, U.S. Supreme Court

- 8 balanced the interests and said protective orders are
- 9 appropriate.
- 10 And, so, moving on to the other individuals here, the
- 11 arguments raised by all of the other parties are essentially
- 12 that they are not parties in the underlying action, but we
- 13 have submitted clear evidence confirming that we believe these
- 14 individuals have all aided and abetted Mr. Gottstein and
- 15 Dr. Egilman in the dissemination of documents protected by
- 16 CMO-3.
- 17 The fact of the matter is that one of the documents
- 18 we submitted says and we quote: We can all be Jim, and that's
- 19 exactly what they're trying to do here. There have been
- 20 orders issued by the Court. They have done everything in
- 21 their power to evade those orders to put the documents into
- 22 other people's hands or to have other people try to post
- 23 information about them and the information that I'm suggesting
- 24 that I have here relates to David Oaks who is the director of
- 25 Mind Freedom who is in constant communication with the

- 1 contributors to the pbwiki and he's telling them please post
- 2 this to the wiki. How do I get the information out
- 3 anonymously? People working on the pbwiki are aiding and
- 4 abetting Mind Freedom, David Oaks, director of Mind Freedom,
- 5 and the intentional violation of this Court's December 29th
- 6 order.
- And, so, all of the people, Terry Gottstein,

- 8 Mr. Gottstein, Judy Chamberlin, Robert Whittiker, all of those
- 9 people had notice and opportunity to be heard on the 3rd.
- 10 They either did not appear or they did appear and argued. The
- 11 motion for reargument is not met here. There's no new facts
- 12 and no new clear controlling law that modifies it.
- 13 On the issue of the Court's ability to extend these
- 14 issues as it previously did, which is to the 16th, the
- 15 standards in the 2d Circuit for temporary restraining order
- 16 and preliminary injunction are the same. All the Court needs
- 17 to identify is that there is a compelling interest that must
- 18 be preserved and there would be irreparable harm if not for
- 19 the injunction or restraining order.
- 20 The courts are clear in the 2d Circuit that the
- 21 protection of trade secrets is something that needs to be
- 22 protected. If it is not protected you have irreparable harm.
- 23 The second issue is whether there is success on the
- 24 merits, which we believe we will be able to establish, or,
- 25 second, the need for a fair and fuller hearing. The parties

- 1 have already said on January 3rd, if a more fair and full
- 2 hearing is necessary, that's why the original hearing was
- 3 scheduled for the 16th and, so, your Honor, is well within its
- 4 discretion to deal with the specific issues raised today,
- 5 which are whether there's factual matters that were not --
- 6 that could have been but were not presented to the Court and
- 7 whether it is clear error and we don't think either of those
- 8 is present.

- 9 So, we ask that the injunction or preliminary
- 10 injunction be continued until January 16th at two o'clock,
- 11 when we can hear the First Amendment issues which we really,
- 12 quite frankly, saw for the first time this morning at 9 a.m.
- 13 THE COURT: Thank you. Does anybody on the phone
- 14 wish to briefly speak? I think I have the full positions of
- 15 both parties and if you want to I'll hear you.
- MR. VON LOHMANN: Your Honor, this is Fred Von
- 17 Lohmann.
- 18 Let me respond very briefly to a few of the points
- 19 that were made by I assume Mr. Fahey before the Court. First,
- 20 let me respond to the concern regarding anonymity. I, of
- 21 course, am very sensitive to my client's desire to speak
- 22 anonymously, which, of course, the Court will recognize as a
- 23 constitutionally protected right repeatedly recognized by the
- 24 Supreme Court. At the same time, I certainly understand
- 25 Lilly's concerns as well. That is exactly why I propose a

- 1 clarification of the Court's order that I believe addresses
- 2 both concerns.
- My proposed clarification would have the Court's
- 4 order apply to anyone who is aiding, abetting, participating
- 5 or otherwise within this proper scope of the Court's
- 6 authority.
- My client is quite confident given his relationship
- 8 or non relationship, as it were, to anyone who is a party to

- 9 this case, that if that language were in the Court's order, he
- 10 would be confident he was not covered and would feel free to
- 11 behave and speak freely without any fear of the Court's
- 12 order. Of course, if it turns out that he or anyone else who
- 13 is on this list in fact is in that relationship, aiding,
- 14 abetting, act in concert or participation, to use the language
- 15 from the cases, then Eli Lilly would remain free under the
- 16 revised order to instigate contempt proceedings and be in a
- 17 position where they could try to prove the relationship.
- 18 Again, my client is absolutely confident that he
- 19 would not be found to be within the scope of the order.
- 20 That's the proposed language to clarify the order I hope will
- 21 balance the interest in anonymity against Lilly's interests in
- 22 being able to develop a record.
- 23 The second point I want to emphasize, your Honor, is
- 24 that with respect to whether or not Mr. Oats or Mind Freedom
- 25 may in fact be encouraging others to publicize information,

- 1 the Lilly documents, et cetera, I don't believe that changes
- 2 the analysis in the least. Mr. Oats and Mind Freedom, neither
- 3 of them are parties to the underlying action, neither of them
- 4 are, to the best of my knowledge, subject to CMO-3. They are,
- 5 of course, named in the latest or I should say Mind Freedom is
- 6 named in the latest court order. However, I found no case to
- 7 suggest that the Court's injunctive authority reaches to
- 8 parties and nonparties and nonparties who aided and abet
- 9 nonparties. At some point this tenuous, tertiary chain has to

- 10 end, otherwise the Court's power would be against the whole
- 11 world, which is exactly what Judge Learned Hand in the
- 12 Alamine (ph.) Manufacturing case made clear cannot be the
- 13 case.
- 14 A third point I want to make briefly, Mr. Fahey
- 15 suggests all of this can wait until the Court's January 16th
- 16 hearing. Well, I'm afraid as Judge Merritt made clear in the
- 17 Proctor & Gamble case, that is not acceptable in a case
- 18 involving a prior restraint and, in fact, Mr. Fahey recites
- 19 the standard for granting temporary restraining order and
- 20 notes it is the same as a preliminary injunction.
- 21 Well, that standard is precisely and expressly
- 22 rejected in the Proctor & Gamble case itself, where Judge
- 23 Merritt points out while that standard may be acceptable in
- 24 cases not involving a prior restraint on speech, that standard
- 25 is not the appropriate standard where prior restraints are

- 1 concerned and he specifically lays out the appropriate
- 2 standard and requires that the party seeking a prior restraint
- 3 must show that the interests involved are more fundamental
- 4 than the First Amendment itself and I am quite confident that
- 5 Lilly has made no showing that rises to that level here.
- 6 And Lilly in their brief and in their argument here
- 7 today suggested they have trade secrets on the line. On that
- 8 question I direct the Court's attention to the Bridge CAT Scan
- 9 case, a 2d Circuit case cited in our brief, where the 2d

- 10 Circuit specifically says it is inappropriate for a party to
- 11 recite a trade secret interest to support an injunction
- 12 against free speech where the underlying action has nothing to
- 13 do with trade secret.
- Again, to the best of my knowledge, the underlying
- 15 product liability litigation here is not a trade secrets case
- $16\,\,$  and I'm not aware of any case where a party is entitled to
- 17 recite this completely separate interest that's collateral to
- 18 the underlying ruling.
- 19 If Lilly believes its trade secrets are on the line
- 20 here, it is free to instigate separate action and seek
- 21 injunctions to protect those interests in a different Court
- 22 and that's not, I think, a basis for granting prior restraint
- 23 here.
- 24 Finally, your Honor, if you are not inclined to
- 25 revise your ruling, as we mention in our brief, we would

- 1 request in the alternative a stay pending our seeking mandamus
- 2 relief from the 2d Circuit. So, I just want to ask once again
- 3 respectfully for a stay in the event the Court rules in that
- 4 manner.
- 5 MR. MILSTEIN: Judge, this is Alan Milstein again for
- 6 Vera Sharav and AHRP. If I can respond briefly to one point?
- 7 I know we're going to deal with some of this on the 16th, but
- $8\,$  the allegation of trade secrets is what I need to talk about.
- 9 This isn't a case where Lilly is afraid that these
- 10 documents are going to be in the hands of their competitors.

- 11 This is a case in which Lilly is afraid that these documents
- 12 are going to be in the hands of consumers who might purchase
- 13 their product.
- 14 THE COURT: Excuse me.
- MR. MILSTEIN: These consumers might find out
- 16 information about the product that might make them fear or
- 17 decide not to take the product.
- 18 THE COURT: Excuse me.
- 19 MR. MILSTEIN: This is a trade secrets case, this
- 20 is --
- THE COURT: Excuse me, sir. I'm not interested in
- 22 the trade secret argument. It is irrelevant to this
- 23 discussion.
- 24 MR. MILSTEIN: Okay.
- MR. CHABASINKSI: May I speak again, your Honor?

- 1 This is Ted Chabasinksi.
- 2 THE COURT: Yes.
- 3 MR. CHABASKINSKI: I haven't received a copy, as I
- $^4\,$  said, of the brief the defendants filed this morning, but I
- 5 heard Mr. Fahey recite one thing that troubles me. He says
- 6 they have submitted clear evidence that the respondent,
- 7 including my clients, aided and abetted this alleged violation
- 8 of the protective order. I haven't seen any such evidence.
- 9 They have huge resources, as I think you can take judicial
- 10 notice of. In eight days, ten days, or whatever number of

- 11 days they got the temporary restraining order, they surely
- 12 could have come up with something more than just that my
- 13 clients received some documents from Mr. Gottstein. And I
- 14 think Mr. Von Lohmann made a good point, it becomes more and
- 15 more tenuous.
- 16 We have nonparties allegedly acting in concert with
- 17 other nonparties who then allegedly aided and abetted
- 18 something it hasn't yet found to have happened. The only
- 19 thing that connects my client with this case --
- 20 THE COURT: Excuse me. I don't want to hear that
- 21 argument again.
- MR. CHABASINSKI: All right, your Honor.
- 23 MR. FAHEY: Your Honor, if I could just --
- THE COURT: No, I don't want to hear any further
- 25 argument at this time.

- 1 As all these attorneys know, an interlocutory
- 2 decision under Section 1292 of Title 28 is appealable. The
- 3 words are "granting, continuing, modifying, refusing or
- 4 dissolving injunctions, or refuses to dissolve or modify
- 5 injunctions".
- 6 If the parties wish, I can characterize this as a
- 7 preliminary injunction, although I don't think it is necessary
- 8 to do so.
- 9 In any event, as counsel has already pointed out,
- 10 mandamus is certainly available, but so is, I believe, an
- 11 appeal, but that is for the attorneys to decide.

- Now, we'll have full argument on all legal issues and
- 13 a full evidentiary hearing on January 16th, 2007 at 2:00 p.m.
- 14 The reason for putting it off until January 16th is because a
- 15 number of the parties wished additional time with respect to
- 16 the matter.
- 17 At that time I will hear all of your arguments and
- 18 all evidence. If you're going to have any witnesses, please,
- 19 give each other notice of the witnesses and the substance of
- 20 the testimony. If you have any documents or other materials,
- 21 do the same so that we can proceed expeditiously with the
- 22 hearing. We're starting late in the afternoon because we have
- 23 some Alaska people and people from the Pacific Coast, which is
- 24 on a different time line than the Eastern District of New
- 25 York. So, we can proceed into the early evening and then

- 1 start the next afternoon.
- I find that Lilly has a substantial probability of
- 3 success on the merits in obtaining appropriate relief in these
- 4 proceedings and that it will suffer irreparable harm without
- 5 appropriate action by the Court.
- I emphasize, as I did at the hearing on January 3rd,
- 7 that I have made no findings nor have I even decided who has
- 8 the burdens of proof. If Lilly expects to proceed by
- 9 contempt, I should like to know against which parties and on
- 10 which issues, because the Court would prefer to expedite
- 11 discovery on any procedures for contempt or for modification

- 12 or for dissolving of the injunction so that the matter can be
- 13 taken up by the Court of Appeals on the fullest possible
- 14 record as soon as possible.
- 15 I should like to emphasize again, as I did I thought
- 16 on the 3rd, that no one is enjoined from discussing anything
- 17 they wish to discuss. New York Times is not enjoined from
- 18 doing anything it wishes to do. The injunction only covers
- 19 the publication and the cooperation in publishing particular
- 20 material which is alleged to have been stolen in violation of
- 21 this Court's orders.
- So, I really don't see at this moment how free speech
- 23 of anybody is affected, but my mind is open on the matter. It
- 24 is an important matter and I will be glad to have full briefs,
- 25 full argument and full evidence beginning on the 16th. I've

- 1 set down for a status conference on Zyprexa cases for
- 2 discussion of some settlement and other related matters and
- 3 I'll have to hold both hearings, but I would appreciate
- 4 counsel being available. I'm sure that they understand that
- 5 the Court has other matters and they will be cooperative.
- 6 So, if you will get in touch with Ms. June Lowe --
- 7 you have her phone number, (718) 613-2525 -- she'll give you
- 8 every possible assistance in communicating. I would be happy
- 9 to have counsel physically present. Obviously, it is easier
- 10 to deal with this matter where I can hold up my hand and stop
- 11 you from talking rather than shouting. If we have witnesses,
- 12 I'll hear them by phone, but again I would prefer to see them

- 13 in person.
- 14 Is there anything else that anybody on the phone
- 15 wishes to bring up before I adjourn?
- 16 (No response.)
- 17 THE COURT: Anybody present wishes to bring anything
- 18 up?
- 19 MR. FAHEY: Your Honor, I just don't know where we
- 20 left the John Doe issue. Whether the EFF client should at
- 21 least disclose to the people involved in this hearing the
- 22 identity of the person?
- THE COURT: I'm not so ordering it at this time, no.
- 24 MR. FAHEY: Okay.
- THE COURT: You have your resources for investigation

- 1 and it is a matter we can take up on the 16th.
- MR. FAHEY: Thank you, your Honor.
- 3 THE COURT: I do not want this sensitive and
- 4 difficult case handled with letters. I do not want any of you
- 5 calling my law clerk. If you want to communicate, please do
- 6 it in writing and if you want information, please do it with
- 7 the case coordinator, Ms. June Lowe.
- 8 Is there anything else, any question that you have?
- 9 MR. CHABASINSKI: Yes, your Honor. Regarding what
- 10 you just said about not contacting your law clerk, I know
- 11 you've already chided me for my rather informal method of
- 12 communicating.

- 13 THE COURT: I haven't chided you. I told you I
- 14 prefer to get briefs and written material and I did not
- 15 appreciate you sending a letter to the Court without a copy to
- 16 the parties.
- 17 MR. CHABASINSKI: I apologize, your Honor. I did
- 18 copy the last letter.
- 19 THE COURT: When you do so, please put it on your
- 20 letter. It is, as I understand it, ordinary professional
- 21 practice.
- MR. CHABASINSKI: Yes, your Honor.
- 23 THE COURT: I'm not chiding you, I don't even know
- 24 you.
- MR. CHABASINSKI: I want to make sure I am proceeding

- $1\,\,$  the way you want me to. I want to tell you this morning I
- 2 called your law clerk only to find out about whether certain
- 3 papers had been filed.
- 4 THE COURT: It is perfectly appropriate.
- 5 MR. CHABASINSKI: Please tell me what you prefer I
- 6 do.
- 7 THE COURT: Call Ms. June Lowe. She's just in charge
- 8 of case coordination, she is not in charge of
- 9 decision-making. I think we all know the difference between
- 10 an elbow law clerk and a case coordinator.
- MR. CHABASINSKI: Yes, your Honor.
- 12 THE COURT: Both are vital, but they are not the
- 13 same.

14	All right, thank you very much.	I will see you or
15	hear from you on the 16th. Good night.	
16	(Proceedings concluded.)	
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### **EXHIBIT F**

### UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK

In re:	07-CV- 0504 (JBW)
ZYPREXA LITIGATION	

#### DECLARATION OF LAURA R. MASON IN SUPPORT OF NONPARTIES' PROPOSED FINDINGS OF FACT AND OBJECTIONS TO ELI LILLY'S AMENDED PROPOSED FINDINGS OF FACT.

#### I, LAURA R MASON, declare as follows:

I am a law student at the UC Berkeley School of Law (Boalt Hall). I am also an intern at the Electronic Frontier Foundation. I make this declaration based upon my personal knowledge.

- 2. On February 1, 2007, I sought to determine whether the Eli Lilly documents continue to be available on the Internet. To that end, I conducted a search on the Google search engine using "link: zyprexakills.tar.gz" as my search terms. The search returned 85 results. Among these results, the Eli Lilly documents were available for download in six locations.
- 3. The search results included two websites where the documents were available for direct download:
  - a. Rob Wipond is a Canadian journalist. I successfully downloaded the Eli
    Lilly documents from his website's main page, located at
    http://www.robwipond.com.
  - b. http://zyprexakills.ath.cx. The Eli Lilly documents continue to be available for download on the "Zyprexa Kills" website. The address of the site ends in

- a ".cx" top-level domain, suggesting that it is hosted on a server on Christmas Island, a territory of Australia. Using the link provided on the main page of the website, I successfully downloaded the Eli Lilly documents.
- 4. The Pirate Bay is a website that coordinates the distribution of information among individuals using the file-sharing technology known as BitTorrent. I successfully downloaded the Eli Lilly documents from the page located at http://thepiratebay.org/tor/3589817/ZyprexaKills.tar.gz. The webpage indicates that, as of February 1, the documents had been downloaded 115 times using the link provided.
- 5. Also among the results were three online BitTorrent directories with links to the Eli Lilly documents. BitTorrent directories do not host complete files, but instead provide links that allow users to download files using the BitTorrent network.
  - a. On TorrentReactor, the Eli Lilly documents were available for download at http://www.torrentreactor.net/view.php?id=719716&display=detailed. The webpage indicates that, as of February 1, the documents had been downloaded 100 times using the link provided.
  - b. On Btjunkie, the Eli Lilly documents were available for download at http://btjunkie.org/torrent?do=stat&id=432479a49765d5b796936d9be87968e d83fbc7eeb5f0.
    - On TorrentPortal, the Eli Lilly documents were available for download at http://www.torrentportal.com/details/866493/ZyprexaKills.tar.gz.torrent.
- 6. The results also included two websites with pages explaining how to download the Eli Lilly documents by conducting online searches:

- a. The Furious Seasons website had a page explaining how to download the Eli Lilly documents by conducting a search on the Google search engine. That page is located at http://www.furiousseasons.com/archives/2007/01/the\_zyprexa\_chronicles\_jud ge\_rules\_against\_links\_to\_documents.html.
- b. The Boing Boing website also included a comment describing how to find the documents by conducting a search on the Google search engine. That page is located at http://www.boingboing.net/2007/01/15/eff\_defends\_wikis\_fr.html.
- 7. Finally, two websites appearing in the search results provided links to the Pirate Bay tracker described in paragraph 4 above:
  - a. The Digg website had a page where a site visitor posted a comment with a link to the Pirate Bay download site. That page is located at http://digg.com/politics/EFF\_Defends\_Right\_to\_Link\_from\_Internet\_Wiki. I followed the link and arrived at the same Pirate Bay page where, as noted in paragraph 4 above, I successfully downloaded the Eli Lilly documents.
  - b. The Techdirt website also had a page where a site visitor posted a comment with a link to the Pirate Bay download site. That page is located at http://www.techdirt.com/article.php?sid=20070108/200759. I followed the link and arrived at the same page on the Pirate Bay website where, as noted in paragraph 4 above, I successfully downloaded the Eli Lilly documents.
- 8. Where I was able to successfully download the documents, I examined them and determined that they appear to be the documents in the *New York Times* article published on December 17, 2006.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this declaration is made and executed by me in San Francisco, California, on February 6, 2007

Laura R. Mason

# UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK

In re:
ZYPREXA PRODUCTS LIABILITY LITIGATION
THIS DOCUMENT RELATES TO:
ALL CASES

No. 04-MDL-01596

# DECLARATION OF LAURA R. MASON IN SUPPORT OF JOHN DOE'S SUPPLEMENTAL BRIEF FOR CLARIFICATION OF INJUNCTION

I, LAURA R. MASON, declare as follows:

- I am a law student at the UC Berkeley School of Law (Boalt Hall). I am also an intern at the Electronic Frontier Foundation. I make this declaration based upon my personal knowledge.
- On January 9, 2007, I successfully downloaded the Zyprexa memos from two separate locations.
- 3. To determine whether copies of the Zyprexa memos are available on the internet, I visited Wikipedia, an online encyclopedia located at http://www.wikipedia.org. Using "Zyprexa" as a search term, I found an entry on the site devoted to Olanzapine and Zyprexa.
- 4. Entries on Wikipedia are organized by topic. Under the "Legal" topic section I found two footnotes with links to locations where I was able to download the Zyprexa memos:

- a. Footnote 8 provides a link to a site where the Zyprexa memos can be downloaded using a program called Tor.
  - i. Tor is a free software program that enables users to communicate anonymously through the internet. It also allows users to anonymously post information for others to download.
  - ii. Using Tor, I was able to download the Zyprexa memos at the above listed site.
- b. Footnote 10 provides a link to a site where the Zyprexa memos can be downloaded using a program called Bit Torrent.
  - i. The address of the site ends in a ".cx" top-level domain, suggesting that the site is hosted on a server on Christmas Island, a territory of Australia.
  - Bit Torrent is a free software program that allows users to efficiently download and share files on the internet.
  - iii. Using Bit Torrent, I was able to download the Zyprexa memos at the above listed site.
- 5. On both sites, the Zyprexa memos were available for download as a single compressed file with the filename "ZyprexaKills.tar." File compression is commonly used to place multiple documents into a single output file. The single output file is called an "archive." The process of opening an archive is known as "extraction." I was able to extract the Zyprexa memos using a free software program called PowerArchiver.

- 6. Each archive contains 356 TIFF files and 2 PDF files. The documents in the two archives appear to be identical.
- An examination of a random sample of the files suggests that these are the internal Eli Lilly documents referenced in the series of articles regarding Zyprexa recently published by *The New York Times*.
  - a. File ZY1 00008872, from the "Zyprexa Physician Strategy and Consulting Conference," contains an analysis of the weight gain experienced by patients taking Zyprexa.
  - b. File ZY1 00090009 is entitled "Defending Zyprexa on Hyperglycaemia/Diabetes."
  - c. File ZY1 00649495 is Jason's Streit's "Analysis of U.S. Data (1/1/99 12/31/99) Regarding Olanzapine and Hyperglycemia."

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this declaration is made and executed by me in San Francisco, California, on January 11, 2007.

Haura R. Mason

### **EXHIBIT G**

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December 17, 2006

# Eli Lilly Said to Play Down Risk of Top Pill

By ALEX BERENSON

The drug maker Eli Lilly has engaged in a decade-long effort to play down the health risks of Zyprexa, its best-selling medication for schizophrenia, according to hundreds of internal Lilly documents and e-mail messages among top company managers.

The documents, given to The Times by a lawyer representing mentally ill patients, show that Lilly executives kept important information from doctors about Zyprexa's links to <u>obesity</u> and its tendency to raise blood sugar — both known risk factors for <u>diabetes</u>.

Lilly's ewn published data, which it told its sales representatives to play down in conversations with doctors, has shown that 30 percent of patients taking Zyprexa gain 22 pounds or more after a year on the drug, and some patients have reported gaining 100 pounds or more. But Lilly was concerned that Zyprexa's sales would be hurt if the company was more forthright about the fact that the drug might cause unmanageable weight gain or diabetes, according to the documents, which cover the period 1995 to 2004.

Zyprexa has become by far Lilly's best-selling product, with sales of \$4.2 billion last year, when about two million people worldwide took the drug.

Critics, including the American Diabetes Association, have argued that Zyprexa, introduced in 1996, is more likely to cause diabetes than other widely used schizophrenia drugs. Lilly has consistently denied such a link, and did so again on Friday in a written response to questions about the documents. The company defended Zyprexa's safety, and said the documents had been taken out of context.

But as early as 1999, the documents show that Lilly worried that side effects from Zyprexa, whose chemical name is olanzapine, would hurt sales.

"Olanzapine-associated weight gain and possible hyperglycemia is a major threat to the long-term success of this critically important molecule," Dr. Alan Breier wrote in a November 1999 e-mail message to two-dozen Lilly employees that announced the formation of an "executive steering committee for olanzapine-associated weight changes and hyperglycemia." Hyperglycemia is high blood sugar.

At the time Dr. Breier, who is now Lilly's chief medical officer, was the chief scientist on the Zyprexa program.

In 2000, a group of diabetes doctors that Lilly had retained to consider potential links between Zyprexa and diabetes warned the company that "unless we come clean on this, it could get much more serious than we might anticipate," according to an e-mail message from one Lilly manager to another.

And in that year and 2001, the documents show, Lilly's own marketing research 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.

The documents were collected as part of lawsuits on behalf of mentally ill patients against the company. Last year, Lilly agreed to pay \$750 million to settle suits by 8,000 people who claimed they developed diabetes or other medical problems after taking Zyprexa. Thousands more suits against the company are pending.

On Friday, in its written response, Lilly said that it believed that Zyprexa remained an important treatment for patients with schizophrenia and <u>bipolar disorder</u>. The company said it had given the <u>Food and Drug Administration</u> all its data from clinical trials and reports of adverse events, as it is legally required to do. Lilly also said it shared data from literature reviews and large studies of Zyprexa's real-world use.

"In summary, there is no scientific evidence establishing that Zyprexa causes diabetes," the company said.

Lilly also said the documents should not have been made public because they might "cause unwarranted fear among patients that will cause them to stop taking their medication."

As did similar documents disclosed by the drug maker <u>Merck</u> last year in response to lawsuits over its painkiller Vioxx, the Lilly documents offer an inside look at how a company marketed a drug while seeking to play down its side effects. Lilly, based in Indianapolis, is the sixth-largest American drug maker, with \$14 billion in revenue last year.

The documents — which include e-mail, marketing material, sales projections and scientific reports — are replete with references to Zyprexa's importance to Lilly's future and the need to keep concerns about diabetes and obesity from hurting sales. But that effort became increasingly difficult as doctors saw Zyprexa's side effects, the documents show.

In 2002, for example, Lilly rejected plans to give psychiatrists guidance about how to treat diabetes, worrying that doing so would tarnish Zyprexa's reputation. "Although M.D.'s like

objective, educational materials, having our reps provide some with diabetes would further build its association to Zyprexa," a Lilly manager wrote in a March 2002 e-mail message.

But Lilly did expand its marketing to primary care physicians, who its internal studies showed were less aware of Zyprexa's side effects. Lilly sales material encouraged representatives to promote Zyprexa as a "safe, gentle psychotropic" suitable for people with mild mental illness.

Some top psychiatrists say that Zyprexa will continue to be widely used despite its side effects, because it works better than most other antipsychotic medicines in severely ill patients. But others say that Zyprexa appears no more effective overall than other medicines.

And some doctors who specialize in diabetes care dispute Lilly's assertion that Zyprexa does not cause more cases of diabetes than other psychiatric drugs. "When somebody gains weight they need more insulin, they become more insulin resistant," Dr. Joel Zonszein, the director of the clinical diabetes center at Montefiore Medical Center in the Bronx, said when asked about the drug.

In 2003, after reviewing data provided by Lilly and other drug makers, the F.D.A. said that the current class of antipsychotic drugs may cause high blood sugar. It did not specifically single out Zyprexa, nor did it say that the drugs had been proven to cause diabetes.

The drugs are known as atypical antipsychotics and include Johnson & Johnson's Risperdal and AstraZeneca's Seroquel. When they were introduced in the mid-1990s, psychiatrists hoped they would relieve mental illness without the tremors and facial twitches associated with older drugs. But the new drugs have not proven significantly better and have their own side effects. said Dr. Jeffrey Lieberman, the lead investigator on a federally sponsored clinical trial that compared Zyprexa and other new drugs with one older one.

The Zyprexa documents were provided to the Times by James B. Gottstein, a lawyer who represents mentally ill patients and has sued the state of Alaska over its efforts to force patients to take psychiatric medicines against their will. Mr. Gottstein said the information in the documents raised public health issues.

"Patients should be told the truth about drugs like Zyprexa," Mr. Gottstein said.

Lilly originally provided the documents, under seal, to plaintiffs lawyers who sued the company claiming their clients developed diabetes from taking Zyprexa. Mr. Gottstein, who is not subject to the confidentiality agreement that covers the product liability suits, subpoensed the documents in early December from a person involved in the suits.

In its statement, Lilly called the release of the documents "illegal." The company said it could

not comment on specific documents because of the continuing product liability suits.

In some ways, the Zyprexa documents are reminiscent of those produced in litigation over Vioxx, which Merck stopped selling in 2004 after a clinical trial proved it caused heart problems. They treat very different conditions, but Zyprexa and Vioxx are not entirely dissimilar. Both were thought to be safer than older and cheaper drugs, becoming bestsellers are a result, but turned out to have serious side effects.

After being pressed by doctors and regulators, Merck eventually did test Vioxx's cardiovascular risks and withdrew the drug after finding that Vioxx increased heart attacks and strokes.

Lilly has never conducted a clinical trial to determine exactly how much Zyprexa raises patients' diabetes risks. But scientists say conducting such a study would be exceedingly difficult, because diabetes takes years to develop, and it can be hard to keep mentally ill patients enrolled in a clinical trial.

When it was introduced, Zyprexa was the third and most heralded of the atypical antipsychotics. With psychiatrists eager for new treatments for schizophrenia, bipolar disorder, and dementia, Zyprexa's sales soared.

But as sales grew, reports rolled in to Lilly and drug regulators that the medicine caused massive weight gain in many patients and was associated with diabetes. For example, a California doctor reported that 8 of his 35 patients on Zyprexa had developed high blood sugar, including two who required hospitalization.

The documents show that Lilly encouraged its sales representatives to play down those effects when talking to doctors. In one 1998 presentation, for example, Lilly said its salespeople should be told, "Don't introduce the issue!!!" Meanwhile, the company researched combinations of Zyprexa with several other drugs, hoping to alleviate the weight gain. But the combinations failed.

To reassure doctors, Lilly also publicly said that when it followed up with patients who had taken Zyprexa in a clinical trial for three years, it found that weight gain appeared to plateau after about nine months. But the company did not discuss a far less reassuring finding in early 1999, disclosed in the documents, that blood sugar levels in the patients increased steadily for three years.

In 2000 and 2001, more warning signs emerged, the documents show. In four surveys conducted by Lilly's marketing department, the company found that 70 percent of psychiatrists polled had seen at least one of their patients develop high blood sugar or diabetes while taking Zyprexa, compared with about 20 percent for Risperdal or Seroquel. Lilly never disclosed those

findings.

By mid-2003, Lilly began to change its stance somewhat, publicly acknowledging that Zypress can cause severe obesity. Marketing documents make clear that by then Lilly believed it had no choice. On June 23, 2003, an internal committee reported that Zyprexa sales were "below plan" and that doctors were "switching/avoiding Zyprexa."

Since then, Lilly has acknowledged Zyprexa's effect on weight but has argued that it does not necessarily correlate to diabetes. But Zyprexa's share of antipsychotic drug prescriptions is falling, and some psychiatrists say they no longer believe the information Lilly offers.

"From my personal experience, at first my concerns about weight gain with this drug were very significantly downplayed by their field representatives," said Dr. James Phelps, a psychiatrist in Corvallis, Or. 'Their continued efforts to downplay that, I think in retrospect, was an embarrassment to the company."

Dr. Phelps says that he tries to avoid Zyprexa because of its side effects but sometimes still prescribes it, especially when patients are acutely psychotic and considering <u>suicide</u>, because it works faster than other medicines.

"I wind up using it as an emergency medicine, where it's superb," he said. "But I'm trying to get my patients off of Zyprexa, not put them on."

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