EXHIBIT A

As all these attorneys know, an interlocutory decision under Section 1292 of Title 28 is appealable. The words are "granting, continuing, modifying, refusing or dissolving injunctions, or refuses to dissolve or modify injunctions".

If the parties wish, I can characterize this as a preliminary injunction, although I don't think it is necessary to do so.

In any event, as counsel has already pointed out, mandamus is certainly available, but so is, I believe, an appeal, but that is for the attorneys to decide.

Now, we'll have full argument on all legal issues and a full evidentiary hearing on January 16th, 2007 at 2:00 p.m. The reason for putting it off until January 16th is because a number of the parties wished additional time with respect to the matter.

At that time I will hear all of your arguments and all evidence. If you're going to have any witnesses, please, give each other notice of the witnesses and the substance of the testimony. If you have any documents or other materials, do the same so that we can proceed expeditiously with the hearing. We're starting late in the afternoon because we have some Alaska people and people from the Pacific Coast, which is on a different time line than the Eastern District of New York. So, we can proceed into the early evening and then

start the next afternoon.

I find that Lilly has a substantial probability of

success on the merits in obtaining appropriate relief in these proceedings and that it will suffer irreparable harm without appropriate action by the Court.

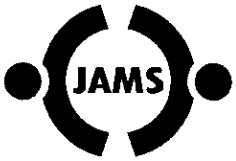
I emphasize, as I did at the hearing on January 3rd, that I have made no findings nor have I even decided who has the burdens of proof. If Lilly expects to proceed by contempt, I should like to know against which parties and on which issues, because the Court would prefer to expedite discovery on any procedures for contempt or for modification or for dissolving of the injunction so that the matter can be taken up by the Court of Appeals on the fullest possible record as soon as possible.

I should like to emphasize again, as I did I thought on the 3rd, that no one is enjoined from discussing anything they wish to discuss. New York Times is not enjoined from doing anything it wishes to do. The injunction only covers the publication and the cooperation in publishing particular material which is alleged to have been stolen in violation of this Court's orders.

So, I really don't see at this moment how free speech of anybody is affected, but my mind is open on the matter. It is an important matter and I will be glad to have full briefs, full argument and full evidence beginning on the 16th. I've

set down for a status conference on Zyprexa cases for discussion of some settlement and other related matters and I'll have to hold both hearings, but I would appreciate counsel being available. I'm sure that they understand that the Court has other matters and they will be cooperative.

EXHIBIT B



www.jamsadr.com THE RESOLUTION EXPERTS Offices Nationwide

Peter H. Woodin
212.607.2736
pwoodin@jamsadr.com

February 1, 2007

VIA FAX: (718) 613-2527

The Honorable Jack B. Weinstein
United States District Judge
United States Courthouse
Eastern District of New York
225 Cadman Plaza East
Brooklyn, New York 11201

Re: In re Zyprexa Product Liability Litigation (MDL 1596)

Dear Judge Weinstein:

I write in my capacity as court-appointed Special Discovery Master in the Zyprexa multidistrict litigation. In prior orders of the Court, James Gottstein, Esq., was directed to take certain steps to secure the return of documents that had been produced by Eli Lilly and Company under the protections of CMO-3, and which Mr. Gottstein had subsequently received from Dr. David Egilman and then disseminated to various third parties. I write now to update the Court concerning the return to me of those documents.

I list below the individuals who have returned documents to me since Judge Cogan's order of December 18, 2006. In every instance documents were returned to me in electronic format, stored on optical discs (CDs and/or DVDs). Along with the names of the individuals who have returned documents to me, I include the date of the return and the number of disks that each individual returned (several individuals returned the original CD mailers from Mr. Gottstein still unopened). In some instances the discs were accompanied by a cover letter or other note; I attach copies of those materials as well.

1. Peter Breggin, 2 discs received January 9, 2007;
2. Will Hall, 1 disc received by hand from John McKay, Esq., January 16, 2007;
3. Grace Jackson, 2 discs received December 20, 2006, with cover note (copy attached);
4. Stefan Kuszewski, 1 unopened CD mailer received January 10, 2007, with cover letter (copy attached);
5. Congressman Henry Waxman, 1 disc received December 22, 2006, with cover letter (copy attached);
6. Bruce Whittington, 1 unopened CD mailer received January 3, 2007, with cover letter (copy attached);
7. Laura Ziegler, 1 disc received December 28, 2006.

In addition to discs received from the above individuals, I have received a total of 10 discs from Mr. Gottstein, either directly or via his counsel, as follows: 7 discs on December 22, 2006; one disc on December 28, 2006; one disc on January 2, 2007; and one disc on January 16, 2007.

Under separate cover, today I am sending to the Court all of the above identified discs.

Respectfully,

Peter H. Woodin
Special Discovery Master

Attachments

cc: John McKay, Esq. (counsel for James Gottstein, Esq.) (via email)
Edward Hayes, Esq., and Alex Reinert, Esq., (Counsel for Dr. David Egilman) (via email)
Evan M. Janush, Esq, Richard D. Meadow, Esq. and William M. Audet, Esq. (for the Plaintiff Steering Committee) (via email)
Nina M. Gussack, Esq., and Sean P. Fahey, Esq.(counsel for Eli Lilly) (via email)

grace jackson

From: grace jackson [gracejackson1@suddenlink.net]
Sent: Tuesday, December 19, 2006 7:51 AM
To: 'Jim Gottstein'
Cc: 'mckay@alaska.net'; 'Peter Woodin'; 'EMJ@lanierlawfirm.com'; 'RDM@lanierlawfirm.com'; 'JamiesonB@LanePowell.com'; 'Faheys@pepperlaw.com'
Subject: RE: Zyprexa Documents

I am mailing these documents to Special Master Woodin via FED EX this morning.
I have not opened any of the documents and possess no copies of them.
Grace E. Jackson, MD

-----Original Message-----
From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, December 19, 2006 2:10 AM
To: grace jackson
Cc: Jim Gottstein; mckay@alaska.net; Peter Woodin; EMJ@lanierlawfirm.com; RDM@lanierlawfirm.com; JamiesonB@LanePowell.com; Faheys@pepperlaw.com
Subject: Zyprexa Documents

Dear Dr. Jackson,

I mailed you DVD (or maybe two) with some documents on them pertaining to Zyprexa and have been orally ordered to have them returned to:

Special Master Peter H. Woodin
JAMS
280 Park Avenue, 28th Floor
New York, New York 10017

A copy of the proposed written order is posted at http://psychrights.org/States/Alaska/CaseXX/EilLilly/ProposedOrder.pdf with a comment about certain language which I strenuously disagree with and we are trying to get eliminated from the signed order. Regardless, please return the DVD, hard copies and any other copies to Special Master Woodin immediately. If you have not yet received it, please return it to Special Master Woodin when you do receive it. In addition, please ensure that no copies exist on your computer or any other computer equipment, or in any other format, website(s) or FTP site(s), or otherwise on the Internet.

There is a question in my mind that the court actually has jurisdiction over me to issue the order. I believe I came into the documents completely legally, but the consequences to me if I am wrong about the jurisdiction issue are severe, so I will very much appreciate your compliance with this request.

Note New E-mail Address

James B. (Jim) Gottstein, Esq.

Law Project for Psychiatric Rights

406 G Street, Suite 206
Anchorage, Alaska 99501
USA
Phone: (907) 274-7686) Fax: (907) 274-9493
jim.gottstein[-at-]psychrights.org
http://psychrights.org/

Psych Rights ®
Law Project for Psychiatric Rights

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of unwarranted forced psychiatric drugging. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Extensive information about this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

NEUROPSYCHIATRY
STEFAN P. KRUSZEWSKI, M.D.

732 Forest Road
Harrisburg, Pennsylvania 17112

T 717-599-5787
F 717-599-5197

skruszewski@spkmd.com
www.spkmd.com

January 9, 2007

Via Overnight Delivery

Special Master Peter H. Woodin
JAMS
280 Park Avenue, 28th Floor
New York, New York 10017

RE: In re: Zyprexa Products Liability Litigation

Dear Master Woodin:

On December 19, 2006, I received an email from Jim Gottstein, an acquaintance, informing me that he had mailed me an unsolicited DVD containing documents Mr. Gottstein had obtained regarding Zyprexa. Mr. Gottstein's email instructed that he was being ordered to contact everyone that he had mailed discs requesting their immediate return. I sent a reply email to Mr. Gottstein the morning of December 19th that I had not received any such documents or DVDs but that if I did receive any such package, I would immediately return them unopened to your attention. A copy of my email exchange with Mr. Gottstein is attached for your reference.

I later received notice that I was named in a Temporary Mandatory Injunction issued December 29, 2006 (later extended until January 16, 2007). Please be advised that I am not a party to the underlying litigation nor do I believe I am subject to the court's jurisdiction in this matter. Further, I believe that these documents are in the public domain and cannot be considered confidential. Despite these concerns, I am however, complying with Mr. Gottstein's request.

Please find enclosed a brown envelope addressed to me from the Pennsylvania Psychiatric Society, postmarked January 3, 2007 which contains an **unopened**, smaller, bubble mailer from Office Depot, also addressed to my attention [albeit incorrectly], that has a return address of PsychRights, 406 G Street, Suite 206, Anchorage, Alaska 99501 and is postmarked December 13, 2006.

The envelope from the Pennsylvania Psychiatric Society was delivered to me on January 4, 2007. At that time, I opened the outside envelope and upon discovery that the bubble mailer from PsychRights was inside, immediately closed the outer envelope. It is my

assumption that the unopened bubble mailer contains the DVD that Mr. Gottstein emailed me about on December 19, 2006. Per Mr. Gottstein's original email request along with the notices that I have received regarding the Injunction and ongoing hearings on this matter, I hereby certify to you and all interested parties that I am voluntarily returning, **unopened**, the envelope sent by Jim Gottstein. I further certify that I have not viewed these documents, nor have I disseminated them in any fashion.

I trust that this submission will satisfy the court in this matter. If you have any questions, please feel free to contact me. Thank you for your prompt attention to this matter.

Sincerely,

Stefan P. Kruszewski, M.D.

Attachment and Enclosures

cc: Jim Gottstein, Esquire (via email and without enclosures)
Sean Fahey, Esquire (via email and without enclosures)

From: Stefan P Kruszewski, MD [skruszewski@spkmd.com]
Sent: Tuesday, December 19, 2006 8:11 AM
To: 'Jim Gottstein'
Subject: RE: Zyprexa Documents
Dear Jim, I have not as yet received any documents or DVDs from you. I will absolutely return anything that I receive from you , unopened. (If you mailed something to me, they might, perhaps, be in my PO BOX in the Linglestown area of Harrisburg...one that neither I nor my staff check every day.) Regardless of the DVD whereabouts, I am also certain that you had the best intentions of patients in hand. I know that you would not have done anything that you even suspected might be contrary to the requirements of the law.

Please let me know if I can do anything else for you in this temporarily uncomfortable time. I am here for you if you need me. Stefan

---

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, December 19, 2006 2:45 AM
To: skruszewski@spkmd.com
Cc: Jim Gottstein; mckay@alaska.net; Peter Woodin; EMJ@lanierlawfirm.com; RDM@lanierlawfirm.com; JamiesonB@LanePowell.com; Faheys@pepperlaw.com
Subject: Zyprexa Documents

Dear Dr. Kruszewski,

I mailed you a DVD or two with some documents on them pertaining to Zyprexa and have been orally ordered to have them returned to:

Special Master Peter H. Woodin
JAMS
280 Park Avenue, 28th Floor
New York, New York 10017

A copy of the proposed written order is posted at http://psychrights.org/States/Alaska/CaseXX/EilLilly/ProposedOrder.pdf with a comment about certain language which I strenuously disagree with and we are trying to get eliminated from the signed order. Regardless, please return the DVD, hard copies and any other copies to Special Master Woodin immediately. If you have not yet received it, please return it to Special Master Woodin when you do receive it. In addition, please ensure that no copies exist on your computer or any other computer equipment, or in any other format, website(s) or FTP site(s), or otherwise on the Internet.

There is a question in my mind that the court actually has jurisdiction over me to issue the order. I believe I came into the documents completely legally, but the consequences to me if I am wrong about the jurisdiction issue are severe, so I will very much appreciate your compliance with this request.

Note New E-mail Address

James B. (Jim) Gottstein, Esq.

Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, Alaska 99501
USA
Phone: (907) 274-7686) Fax: (907) 274-9493
jim.gottstein[-at-]psychrights.org
http://psychrights.org/

Psych Rights ®
Law Project for Psychiatric Rights

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of unwarranted forced psychiatric drugging. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Extensive information about this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

--

--

December 21, 2006

BY FIRST-CLASS MAIL

Special Master Peter H. Woodin
JAMS
280 Park Avenue, 28th Floor
New York, NY 10017

Re: In re: Zyprexa Products Liability Litigation, MDL No. 1596 (E.D.N.Y.)

Dear Special Master Woodin:

I am currently the Ranking Member — and will in January become the Chairman — of the Committee on Government Reform of the U.S. House of Representatives, the House's principal investigative committee. The Government Reform Committee has broad jurisdiction over the operations of the federal government (Rules of the House of Representatives, Rule X.1(h) (109th Cong.)), and general oversight responsibility to "determine whether laws and programs addressing subjects within [its] jurisdiction ... are being implemented and carried out in accordance with the intent of Congress ...." (Rule X.2(b)(1)).

As you may be aware, James B. Gottstein of the Law Project for Psychiatric Rights recently provided the minority staff of the Committee with certain documents related to Zyprexa. Those documents relate to drug safety, a matter within the Committee's oversight jurisdiction.

On Wednesday, December 20, 2006, Mr. Gottstein advised us that the U.S. District Court for the E.D.N.Y. had entered an order in the above-referenced case directing him to "immediately take steps to retrieve any documents subject to th[e] Order, regardless of their current location, and return all such documents to Special Master Woodin." (Order for Mandatory Injunction at 2 (Dec. 18, 2006)). Mr. Gottstein asked that we return to you the documents he provided to the Committee, and delete any copies on Committee computers.

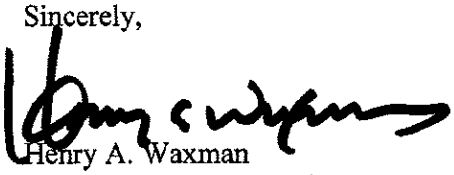
It is my understanding that the District Court's December 18 Order is not directed to the Committee, or any of its Members or staff. Furthermore, any attempt to compel the Committee, or any of its Members or staff to return the documents provided to us by Mr. Gottstein would conflict with the absolute privilege afforded to Members of Congress under the Constitution's

Speech or Debate Clause (U.S. Const. art. I, § 6, cl. 1; See *Eastland v. United States Serviceman's Fund*, 421 U.S. 491 (1975); *Gravel v. U.S.*, 408 U.S. 606 (1972); *Brown & Williamson Tobacco Corp. v. Williams*, 62 F.3d 408 (D.C. Cir. 1995)).

Nevertheless, out of deference to Mr. Gottstein's wishes, and out of a sense of comity and respect for a coordinate branch of the federal government, we are voluntarily returning the documents provided to us by Mr. Gottstein. Enclosed please find a disc of documents. We have also voluntarily deleted all copies of these documents on Committee computers.

Thank you for your attention.

Sincerely,



Henry A. Waxman
Ranking Minority Member

Enclosures

cc: Honorable Tom Davis, Chairman
James B. Gottstein, Esq.

Fahey, Sean P.

From: Peter Woodin [pwoodin@jamsadr.com]
Sent: Thursday, February 01, 2007 5:26 PM
To: 'John McKay'; Fahey, Sean P.; 'Richard D. Meadow'; 'Evan Janush'; 'Bill Audet'; Gussack, Nina; 'Edward Hayes'; 'Alex Reinert'
Subject: RE: Zyprexa: Letter to j. Weinstein re Return of Lilly documents

Follow Up Flag: Follow up
Flag Status: Red

Attachments: Zyprexa - Whittington ltr.pdf

Zyprexa - Whittington ltr.pdf ..

Dear Counsel:

A copy of the letter from Bruce Whittington was inadvertently omitted from my prior email. I attach it hereto.

Peter Woodin

-----Original Message-----
From: Peter Woodin [mailto:pwoodin@jamsadr.com]
Sent: Thursday, February 01, 2007 5:10 PM
To: 'John McKay'; 'Fahey, Sean P.'; 'Richard D. Meadow'; 'Evan Janush'; 'Bill Audet'; Nina Gussack (GUSSACKN@pepperlaw.com); 'Edward Hayes'; 'Alex Reinert'
Subject: Zyprexa: Letter to j. Weinstein re Return of Lilly documents

Dear Counsel:

Please see attached.

Peter Woodin

Peter H. Woodin
JAMS
280 Park Avenue, 28th Floor
New York, NY 10017
Tel: 212-607-2736
Fax: 212-972-0027
Email: pwoodin@jamsadr.com

1044 Gatensbury Rd.
Port Moody, BC V3H 2P2

December 23, 2006

Peter H. Woodin
JAMS
280 Park Ave., 28th Floor
New York, NY 10017

Dear Sir:

Re: Electronic Documents Received From James Gottstein

Enclosed is the DVD-ROM which I received from Mr. Gottstein yesterday, and which he directed that I forward to you.

Sincerely yours,

Bruce Whittington

encl.

EXHIBIT C

list, correct?
A I made two batches.
Q Right, for the next two days, correct?
A In the next two. It wasn't for them. I didn't spend all say two days doing it.
Q This is the question I want to make clear. You were so busy making copies of these documents that you never got to review them, did you?
A I looked at some of them. The deposition was quite -- a few days off which is, I think, your complaint. So I would pull up some of them and look at them and I -- and it wasn't that I was so busy make copies. I had my laptop burning DVDs and my main computer burning DVDs, another laptop making sure that they were -- I would make them and then I would put them in this other one to make sure that they came up and I don't know, I don't think it took me an hour to do it each time. Probably less.
Q And you were anxious to get them out as quickly as you could, right?
A Anxious, yes, I thought it would be good to get them out.
Q Before the Court could enter an order telling you you shouldn't?
A Well, I don't know. I mean I guess -- I don't know that -- you know, I knew that Eli Lilly would want to try to stop it.

Q Right, and you wanted to get them out as quickly as you could to make that harder?

A Well, I would say yeah, I wanted to get them out of the way that would make it impossible to get them back.

Q Right. And I just want to confirm that you, sir, as an officer of the Court and an attorney in the State of Alaska, relied on a physician to determine the legal implications of a protective order, correct?

A No, that is not precisely true. I advised him to get counsel repeatedly and I looked at it in terms of what my obligations were and that I didn't have any obligations under what is called CMO-3 here, I think, the protective order, that I had to follow the rules. I felt that the protective order essentially provided a road map of how to do it and that I followed that road map.

Q Based on Dr. Eagleman's description of that road map, right?

A His -- well, he read that paragraph to me.

Q And let me just -- and the reason why I'm asking the question, you submitted a declaration to the Court this morning?

A Yes.

Q In paragraph 6 of that declaration, you wrote, and these are your words: Dr. Eagleman indicated that three business days could be construed as sufficient notice to comply?

EXHIBIT D

Date	Time	Length (00:00:00)	Number Called	Recipient Name	Egilman Number
08/04/06	2:44 PM	1:00	(917) 650-1745	Berenson, Alex	(508) 969-2849
08/23/06	11:22 AM	12:00	(917) 650-1745	Berenson, Alex	(508) 969-2849
08/28/06	2:56 PM	1:00	(212) 556-7208	Berenson, Alex	(508) 969-2849
08/28/06	3:22 PM	:12	(917) 650-1745	Berenson, Alex	(508) 226-5093
08/31/06	10:59 AM	3:00	(917) 650-1745	Berenson, Alex	(508) 969-2849
09/05/06	2:06 PM	1:00	(212) 556-7208	Berenson, Alex	(508) 969-2849
10/24/06	12:41 PM	1:00	(917) 650-1745	Berenson, Alex	(508) 969-2849
10/25/06	2:05 AM	1:00	(917) 650-1745	Berenson, Alex	(508) 969-2849
10/30/06	1:46 PM	1:00	(917) 650-1745	Berenson, Alex	(508) 969-2849
11/07/06	3:02 PM	:54	(917) 232-3943	Berenson, David	(508) 226-5091
11/07/06	3:13 PM	:48	(917) 232-3943	Berenson, David	(508) 226-5091
11/07/06	3:26 PM	:06	(917) 232-3943	Berenson, David	(508) 226-5091
11/07/06	3:26 PM	:06	(917) 232-3943	Berenson, David	(508) 226-5091
11/10/06	1:39 PM	:54	(917) 650-1745	Berenson, Alex	(508) 226-5091
11/10/06	4:41 PM	:06	(212) 558-7208	Berenson, Alex	(508) 226-5092
11/13/06	5:26 PM	:06	(917) 650-1745	Berenson, Alex	(508) 226-5093
11/13/06	5:27 PM	:06	(212) 558-7208	Berenson, Alex	(508) 226-5092
11/14/06	3:02 PM	1:00	(212) 556-7208	Berenson, Alex	(508) 969-2849
11/14/06	3:18 PM	1:00	(917) 650-1745	Berenson, Alex	(508) 969-2849
11/15/06	4:26 PM	1:00	(917) 650-1745	Berenson, Alex	(508) 969-2849
11/29/06	12:35 PM	3:00	(917) 650-1745	Berenson, Alex	(508) 969-2849
12/13/06	2:16 PM	5:00	(907) 274-7686	Gottstein, James	(508) 969-2849
12/13/06	3:16 PM	11:00	(212) 556-7208	Berenson, Alex	(508) 226-5093
12/14/06	1:16 PM	10:00	(907) 274-7686	Gottstein, James	(508) 969-2849
12/14/06	1:32 PM	3:18	(212) 595-8974	Sharav, Vera	(508) 226-5093
12/14/06	1:43 PM	1:36	(212) 556-7208	Berenson, Alex	(508) 226-5093
12/14/06	1:58 PM	:36	(212) 595-8974	Sharav, Vera	(508) 226-5093
12/14/06	2:04 PM	11:00	(907) 274-7686	Gottstein, James	(508) 969-2849
12/14/06	2:21 PM	:06	(917) 650-1745	Berenson, Alex	(508) 226-5092
12/14/06	2:21 PM	:06	(917) 650-1745	Berenson, Alex	(508) 226-5093
12/15/06	2:02 PM	:48	(917) 650-1745	Berenson, Alex	(508) 226-5093
12/15/06	2:07 PM	:18	(212) 556-7208	Berenson, Alex	(508) 226-5093
12/15/06	4:40 PM	27:30	(907) 274-7686	Gottstein, James	(508) 226-5092

EXHIBIT E

THE COURT: I will rule on that. You may brief it if you wish. We'll get a briefing schedule and I'll rule on it in connection with the evidentiary hearing we have just held.

Now, if in addition you want to proceed pursuant to CMO-3 for the independent release of documents, you can do so, but I don't consider sufficiently formal your papers in the present procedures to raise those issues in the clear cut way that they should be raised.

So I'm not ruling on that but if you intend to proceed along those lines as for example was done in the Agent Orange case where the Court issued an order unsealing, then I suggest you do it in a formal way. I'm not satisfied to approach such an important motion by the informal papers I have now.

MR. MILSTEIN: I'll do that.

I think if the Court denies the preliminary injunction as to my clients, then we can do what we want.

THE COURT: I don't care what you do. I'm just telling you what your position is.

Does anybody wish time to brief this is what I'm asking?

MR. LEHNER: Yes, your Honor.

THE COURT: How much time do you want?

I'd like to bring this to a head because as of

again some reading and research, obviously, looking forward to this hearing and possible subsequent hearings and I do find them very perplexing for the reasons that Mr. Hayes has partly alluded to.

So I suggest if that's what you want to do, set it down for deposition and the proposed deponent will have to decide what he wants to do.

MR. HAYES: Thank you, your Honor.

MR. VON LOHMANN: Your Honor, will that be the close of evidence with respect to this issue?

THE COURT: I'll allow the deposition as well as any documents taken from the Redwell to be submitted to supplement the record we made today and yesterday.

MR. VON LOHMANN: And that will be it?

THE COURT: That will be the end.

MR. HAYES: This is a deposition with regard to this proceeding solely?

THE COURT: Yes, but the difficulty, you understand, is that what is at issue today might well bear on contempt.

MR. HAYES: I understand.

THE COURT: Not so much contempt of this Court's order because there doesn't seem to be strong evidence of contempt of this Court's orders but of the original CMO-3. That is the contempt that is involved.

Yes.

MR. McKAY: I know we want to leave.

THE COURT: I'm perfectly willing. I have nothing to do.

MR. McKAY: I would like to clarify one or two things in the same vein and you directed Lilly a week or 10 days ago to specify their intentions with respect to pursuing contempt sanctions and I would like at this point to know what that is.

There were some preliminary indication last Friday night but I think that it's fair to ask at this point.

THE COURT: I think you should let counsel know as soon as possible and preferably Mr. Hayes because his client hasn't testified.

I think Mr. McKay's client has testified fairly fully and openly.

MR. HAYES: To make it simple, my client is going to take the Fifth Amendment -- if they are going to say possibly they are going to proceed with criminal contempt, my client is going to take the Fifth Amendment.

THE COURT: I don't see any point in bringing him forward and wasting a lot of time. I would think a letter to that effect will have the equivalence of his taking the Fifth for purposes of evidence.

MR. HAYES: Yes.

THE COURT: Do you concede that?

MR. HAYES: I do.

THE COURT: That will save us a lot of time if that is the position.

When are you going to inform Mr. Hayes?

MS. GUSSACK: Your Honor, I believe the evidence that we heard yesterday and today provide a basis for seeking sanctions against Mr. Gottstein as well as against Dr. Egilman.

THE COURT: He wants to know if you are going to proceed with criminal contempt.

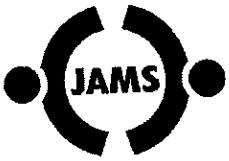
Actually, of course, the concept of criminal and civil contempt is so vague and overlapping that it doesn't make any sense from a conceptual point of view with respect to the issue you are raising. I think anybody who has been in this field knows that but nevertheless, he said that if you don't commit yourself not to proceed with a criminal contempt sanction, his client will plead the Fifth Amendment.

So if you don't want to give him that assurance, tell him that immediately, as soon as you can. He will give you a letter and then that simplifies matters.

MR. McKAY: I'm still asking can they say at this time whether they are not going to pursue criminal contempt against Mr. Gottstein.

THE COURT: They are not in a position to tell you that because he is theoretically in the same position as Mr.

EXHIBIT F



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February 7, 2007

VIA FAX: (718) 613-2527
The Honorable Jack B. Weinstein
United States District Judge
United States Courthouse
Eastern District of New York
225 Cadman Plaza East
Brooklyn, New York 11201

Re: In re Zyprexa Product Liability Litigation (MDL 1596)
UFCW Local 1776 Employers Health and Welfare Fund, et al. v. Eli Lilly and Co. (05-CV-4115, 05-CV-2948) (EDNY)

Dear Judge Weinstein:

I write in my capacity as court-appointed Special Discovery Master in the Zyprexa multidistrict litigation to advise the Court about a challenge to the confidentiality of documents produced by Eli Lilly and Company ("Lilly") under the protections of Case Management Order No. 3 ("CMO 3").

Plaintiffs in the Third Party Payors case have challenged whether various documents produced by Lilly and referenced in the complaint filed in their action deserve the protections of CMO 3. This challenge is pending before me. It is my understanding that various non-parties have similarly challenged the confidentiality under CMO 3 of documents produced by Lilly and subsequently disseminated by James Gottstein, Esq., and that consideration of the non-parties' challenge has been deferred while Lilly's application for an injunction against the further dissemination of the documents remains pending.

It appears likely that various of the documents challenged by the Third Party Payors are among the documents disseminated by Mr. Gottstein, and thus are also the subject of the challenge mounted by the non-parties. Given this overlap, and for the efficient coordination of the Court's consideration of this issue, it would be my recommendation that the Third Party Payors' challenge be similarly deferred, and that both matters be considered together.

Respectfully,

Peter H. Woodin
Special Discovery Master

cc: Thomas M. Sobol, Esq., and Lauren Barnes, Esq. (counsel for Third Party Payors) (via email)
Barry H. Boise, Esq. and Sean P. Fahey, Esq.(counsel for Eli Lilly) (via email)

EXHIBIT G

FIBICH, HAMPTON & LEEBRON, L.L.P.
ATTORNEYS AT LAW
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December 19, 2006

Sean P. Fahey
Pepper Hamilton LLP
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103-2799

Re: MDL 1596; In Re: Zyprexa Products Liability Litigation

Dear Mr. Fahey:

As you know, Bill Audet and I are members of the PSC with Mel Weiss as Chairman. This letter is written on behalf of the PSC to advise you and your client that we strongly support your efforts to prevent the dissemination of any information protected by the confidentiality agreement in this cause. Please ensure that Bill Audet, Mel Weiss or myself is given notice of any matters before the Court on this issue so that our position may be known.

Sincerely,

FIBICH, HAMPTON & LEEBRON, LLP

BY: _____
Kenneth T. Fibich

KTF:rs

Enclosures

cc: Weiss
Audet

EXHIBIT H

J O I N T C E N T E R
AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES

The Adverse Side Effects of Pharmaceutical Litigation

Judyth Pendell

Related Publication 03-22
September 2003

Judyth Pendell is a senior fellow at the AEI-Brookings Joint Center for Regulatory Studies. She thanks Robert Hahn and Adam Sloane for their helpful comments, and the U.S. Chamber of Commerce for its support. The views expressed in this paper reflect those of the author and do not necessarily reflect those of the AEI-Brookings Joint Center for Regulatory Studies or the U.S. Chamber of Commerce.

Executive Summary

Prior research has demonstrated that a fear of unwarranted medical malpractice liability causes doctors and other healthcare practitioners to engage in self-protective activities, such as ordering unnecessary tests or treatments. This paper examines the impact that the liability system could have on prescription drug use. It reports on a Harris poll of doctors, pharmacists and patients. Situations where patients fail to receive appropriate medications as a direct result of the liability system are revealed. It recommends reforms that allow healthcare professionals to know with greater certainty which actions are likely to result in liability.

The Adverse Side Effects of Pharmaceutical Litigation

Judyth Pendell

Introduction

Healthcare is a public policy issue in which everyone has a very personal stake. Individual concerns about whether or not quality care will be available when it is needed commonly focus on whether good doctors and hospitals, and the best technology, will be accessible and affordable. It probably rarely occurs to anyone that even when the best care is within reach it might not be forthcoming because doctors or nurses or pharmacists may have concerns about themselves that trump their concerns about their patients.

Fear of unwarranted malpractice liability claims can create just such a conflict. In 2002, Common Good, an organization headed by lawyer and author Philip Howard, produced new, compelling evidence that doctors and other healthcare professionals are so concerned about unfounded lawsuits that they order unnecessary tests and procedures, and sometimes feel constrained from providing the candor and openness that would serve the patient's best interest.

Building on that work, this paper provides a window into how fear of liability could be getting in the way of patients not receiving medications they should have. The paper discusses first the dominance of non-meritorious suits and how the liability system creates undesirable incentives in the delivery of healthcare generally. It then discusses the findings of a Harris poll in which doctors, pharmacists, and patients are interviewed about how liability over pharmaceuticals is affecting their behaviors relative to prescribing, warning, and compliance with prescriptions.[1] It concludes that the randomness and uncertainty of the liability system is creating perverse incentives, including deterring pharmaceutical companies from research and development in some areas.

Healthcare professionals and pharmaceutical companies should be able to anticipate with some reliability which actions will result in liability being imposed, and which actions will provide protection from liability. Healthcare liability should be

[1] The U.S. Chamber Institute for Legal Reform commissioned Harris Interactive to conduct a study on the issue of pharmaceutical product liability litigation. The study was conducted among three target populations: physicians, pharmacists, and patients. A PowerPoint presentation on "Pharmaceutical Liability Study Report on Findings" prepared for the U.S. Chamber Institute for Legal Reform can be viewed at http://www.aei-brookings.org/admin/pdffiles/phpgm.pdf.

reformed to allow for that predictability. Freedom from fear of liability will restore patient well-being as the dominant priority.

Background

The tort system was always meant to affect the conduct of professionals, businesses, and organizations. The rationale has been that if those who provide goods and services are required to pay for the harm they cause they will be deterred from causing harm. The deterrence theory of tort litigation has recently come under intense scrutiny and criticism, however, among legal scholars. Priest[2] and Viscusi[3] have conducted research that concludes that the tort system does not appear to be making products or the environment safer. Sunstein, Schkade, and Kahneman[4] have questioned whether people really want optimal deterrence. Garber,[5] Schwartz,[6] Green,[7] and Burk[8] have focused on whether the tort system over-deters, whether efforts to protect against liability actually create socially undesirable behavior. For example, Garber's research shows how the tort system may be encouraging undesirable behaviors such as avoidance of R&D in product areas at risk of attracting litigation.[9]

Nowhere is this debate more focused than in the healthcare area. According to Alex Azar, the general counsel of the U.S. Department of Health and Human Services, defensive medicine, or the practice of ordering tests or other procedures solely as a protection against litigation, raises healthcare costs by as much as 70 to 126 billion

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[2] See George L. Priest, "Understanding the Liability Crisis," *Liability: Perspective and Policy* (1988).
[3] See W. Kip Viscusi, "The Social Costs of Punitive Damages Against Corporations in Environmental and Safety Torts," *Geo. L. J.* 285 (1998). P. 87.
[4] See Cass R. Sunstein, David a. Schkade, Daniel Kahneman, "Do People Want Optimal Deterrence?" *Punitive Damages: How Juries Decide* (2002) The concept of optimal deterrence applied here is that which is accepted in the field of law and economics. "People appear to reject the view, widespread within economic analysis, that punishment should be increased beyond compensation where the probability of detection is low, and that compensation is adequate where the probability of detection is 100%."
[5] See Steven Garber, "Product Liability, Punitive Damages, Business Decisions and Economic Outcomes," *Wis. L. Rev.* (1998). P 237.
[6] See Victor E. Schwartz, Mark A. Behrens, Joseph P. Mastrosimone, "Reining in Punitive Damages "Run Wild": Proposals for Reform by Courts and Legislatures," *Brook. L. Rev.* 1003 (1999). P 65.
[7] See Michael D. Green, William B. Schultz, "Tort Law Deference to FDA Regulation of Medical Devices," *Geo. L. J.* 2119 (2000). P 88
[8] See Dan L. Burk, Barbara A. Boczar, "Biotechnology and Tort Liability: A Strategic Industry at Risk," *U. Pitt. L. Rev.* (1994). P. 55.
[9] See Steven Garber, "Liability and Patient Health," Transcript of Conference Sponsored by AEI-Brookings Joint Center and Common Good, March 4, 2003.

dollars a year.[10] Unfortunately, the financial costs are not the entire story. Unnecessary interventions can be invasive, risky, and sometimes painful.

To explore further the importance of the problem of defensive medicine, a recent Harris poll commissioned by Common Good (a healthcare poll hereafter referred to as Harris HC) interviewed physicians, nurses, and hospital administrators to explore how the fear of litigation affects the practice of medicine and the delivery of medical care. It revealed that nearly all physicians and hospital administrators feel that unnecessary or excessive care is very often or sometimes provided because of fear about litigation. Physicians indicated in the poll that fear of malpractice claims causes them (or other physicians) to:

- Order more tests than they would based only on professional judgment of what is medically needed. (91% have noticed other physicians, and 79% report they themselves do this due to concerns about malpractice liability.)
- Refer patients to specialists more often than they would, based only on their professional judgment of what is medically needed. (85% have noticed other physicians, and 74% report they themselves do this due to concerns about malpractice liability).
- Suggest invasive procedures such as biopsies to confirm diagnoses more often then they would, based only on their professional judgment of what is medically needed. (73% have noticed other physicians, and 51% report they themselves do this due to concerns about malpractice liability.)
- Avoid candid discussions of medical mistakes when they are made. (Fear of liability is cited by physicians and hospital administrators as the leading factor that discourages medical professionals from openly discussing and thinking of ways to reduce medical errors.)[11]

Most of the literature on the impact of the liability system on healthcare has focused on defensive medicine in the context of the delivery of care, particularly in relation to diagnostic and treatment procedures. There has been little attention paid to the impact on pharmaceuticals--prescribing, the warnings about side effects, and patient compliance with recommended medications. The Harris HC poll did ask about doctors prescribing more medications than necessary, and it found that doctors prescribe more medications, such as antibiotics, than they would based only on their professional

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[10] See Alex Azar, id. at 4.
[11] See *Fear of Litigation*, Harris Interactive, April 2002.

judgment of what is medically needed. (Some 73% have noticed other physicians, and 41% report they themselves do this due to concerns about malpractice liability.) However, the poll did not ask whether doctors sometimes avoid prescribing certain medications that they deem appropriate for their patients because the medications have or could become targets of litigation. Similarly, although the literature on defensive medicine has focused primarily on the delivery of healthcare in doctors' offices and in hospitals, little is known about the impact of liability on pharmacies and pharmacists' practices.[12]

To fill this void and expand what is known about the impact of liability on healthcare, and on patient well being, the U.S. Chamber of Commerce commissioned a Harris poll of physicians, pharmacists, and patients with the objective of better understanding how the behaviors of individuals within these groups are affected by litigation involving pharmaceuticals (hereafter referred to as Harris PHRM).[13] The survey is based upon 250 interviews with physicians, 251 interviews with pharmacists, and 301 interviews with patients. (The sampling error for this poll is +- 6.9% for physicians, +-6.2% for pharmacists and +-5.6% for patients.) To target patients who are likely to be currently taking medications (or needing to take medications in the future) patients qualified for the poll if they had been diagnosed with at least one of eight specified medical conditions: high cholesterol, hypertension, arthritis, depression, obesity, diabetes, heart disease, or stomach ulcers. The findings of that poll are discussed in this paper, and the entire poll, including detail about the methodology, appears as an attachment.[14]

The Impact of the Fear of Pharmaceutical Litigation on Physician Practices

In most jurisdictions doctors have a duty to warn patients of side effects associated with a drug, and the pharmaceutical companies are relieved of this duty, when

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[12] The Harris poll commissioned by Common Good expanded the prior, almost exclusive, focus of the impact of fear of liability on physician practices to include hospital administrators and nurses. For example, nearly half or 43% of all nurses also feel prohibited or discouraged from doing what they think is right for the patient because of rules or protocols set up for liability protection.

[13] See *Pharmaceutical Liability Study Report on Findings*, Harris Interactive, July 2003.

[14] See http://www.aei-brookings.org/admin/pdffiles/phpgm.pdf.

the pharmaceutical company has provided an adequate warning to the doctor[15]. This "learned intermediary doctrine" first emerged in the 1960s, and is premised on several assumptions:

- physicians can evaluate best an individual patient's medical needs and possible drug sensitivities,
- patients may wish to participate in the decision as to whether or not to take on the risks of a particular drug,
- a physician can provide ongoing supervision of the patient's use of the drug, and
- physicians are best positioned to manage any possible side effects that do occur.

The learned intermediary doctrine does not relieve the manufacturer of the duty to provide adequate warnings of risks associated with specific drugs it merely requires that an adequate warning be given to physicians who might prescribe the drug. The assumption is that physicians will pass on an appropriate warning to their patients.[16]

The communication of warnings, however, has been distorted and complicated by fears of tort liability. According to FDA Commissioner Dr. Mark McClellan, "So long as the product developers we work with are facing an environment in which any adverse outcome can result in a major lawsuit, we may get labels written for lawyers, not doctors and patients. Because risk management often means reducing liability risks not reducing patient risks, there's pressure to make labels read like liability avoidance tools. Instead they should be efficient documents for conveying risk--tools for helping doctors help patients. To protect the health of the public product labels should be written with the patient in mind, not a jury."[17] Three in four (74%) doctors interviewed for the Harris PHRM poll feel that the information contained in the patient packet insert is more complicated than it needs to be--and that product liability litigation plays a critical role in making it complicated. In fact, nine in ten (91%) physicians who think the information is too complicated believe that product liability is the problem.

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[15] See Bernard J. Garbutt III, Melinda e. Hofmann, "Recent Developments in Pharmaceutical Products Liability Law: Failure to Warn, the Learned Intermediary Defense, and Other Issues in the New Millennium," *Food & Drug L.J.* 269 (2003). P. 58 (Pharmaceutical companies can be sued under negligence or strict liability theories for product defects.)

[16] See Laurie K. Marshall, "Keeping the Duty to Warn Patients of the Risks and Side Effects of Mass-Marketed Prescription Drugs Where it Belongs: With Their Physicians," *U. Dayton L. Rev.* 95 (2000). P. 26

[17] Mark B McClellan, MD, PhD, Commissioner, Food and Drug Administration. Speech before the Physician Insurers Association of America, May 24, 2003, Chicago, IL.

Since many patients want to participate in making critical medical decisions it is imperative that patients receive accurate and understandable information about the risks and benefits of medical options. This is particularly true for medications where it is almost always true that there are potential adverse side effects. The specter of liability practically assures that warnings will not be clearly worded in a patient-friendly way.

Unfortunately, the malpractice litigation environment in which doctors take on potential liability for the drugs they prescribe and the warnings they issue is far from rational and predictable. The Harris PHRM poll reveals that doctors unanimously (100%) agree that groundless malpractice litigation, or the threat of it, is a major concern to doctors. Nearly all physicians (99%) are personally concerned that they may be the target of groundless litigation or threat of litigation. Two-thirds of doctors (67%) say that they are personally *very* concerned about groundless litigation. Empirical research gives legitimacy to this fear. A study of general medical malpractice claims in the state of New York conducted by Harvard University revealed that for every claim that is filed by a meritorious plaintiff there are five or six other claims that don't involve either a negligence or an injury or both.[18]

Doctors believe that malpractice lawsuits against them that result from prescriptions they have made occur with some frequency. Two in five (40%) doctors are aware of other physicians who have been sued by patients who have experienced side effects from a prescribed drug, even thought the drug was indicated and properly prescribed, leading them to think this type of litigation is common practice. In fact, most (57%) doctors are concerned that they may be sued by a patient who experiences side-effects from a drug they properly prescribe.

Doctors are handicapped in their efforts to provide adequate warnings to patients by the failure of the courts to defer appropriately to the expertise of the Food and Drug Administration (FDA). Doctors are dependent upon the patient package inserts provided by the pharmaceutical companies and approved by the FDA. The FDA provides an expert and careful review of all drug labeling, and requires that all warnings must be supported by solid scientific evidence. As Daniel E. Troy, general counsel of the Food and Drug Administration, has noted: "The agency [FDA] demands scientific substantiation not only

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[18] See Michele Mello, "Liability and Patient Health," conference sponsored by AEI-Brookings Joint Center, March 4, 2003. The study focused on medical malpractice claims generally, not just on claims involving pharmaceuticals.

for statements concerning the drug's clinical utility, but also for statements of precaution, contraindication, and warning. A statement in the labeling of a prescription drug has been found by FDA to represent the most current and complete scientific information. If a statement has been omitted, it is generally because FDA has not found it scientifically substantiated or necessary to assure safe use of the drug."[19] Yet, taken together, doctors don't get clear and consistent messages from the FDA and from the courts.

The dominance of lawsuits without negligence creates a situation of great uncertainty for doctors. They realize the liability system does not have clearly defined rules, where violating the rules means liability is incurred and compliance with the rules means protection from liability will be granted. Professor George Priest of Yale Law School has often referred to this as the "gotcha" system of liability.

How does this fear affect physicians' choices regarding prescribing medications? A sizable number of physicians (43%) have avoided prescribing a particular drug that was appropriate for a patient because they were aware that it might be involved in product liability litigation. Although most physicians do not observe this as a common occurrence, 28% of surveyed physicians did indicate it happened frequently or very frequently. This is less than one third, but the results occur in a situation where the number of physicians responding affirmatively should be zero. Clearly, all patients want their doctors to base their care on medical considerations, not legal considerations.

Doctors also are aware that patient behavior may be influenced more by information coming from the liability system than by information about risks coming from their own doctors. Two in five (38%) doctors reported in the survey that they know of patients who have stopped taking a medication that was properly prescribed for them because the patient discovered the drug was involved in product liability litigation. About three in ten (29%) doctors have had patients refuse to take a drug properly prescribed for them because they were aware that the drug was involved in product liability litigation. Despite the fact that the liability system does a poor job of keeping out unfounded lawsuits, some patients seem to treat the mere existence of a lawsuit as an indication that a drug is harmful.

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[19] See Dan Troy, *FDLI Update*, Jan/Feb 2003.

The Impact of the Fear of Pharmaceutical Liability on Pharmacists' Behaviors

Historically, pharmacists have been on the liability hook almost solely through errors made in filling prescriptions: mistakes involving failure to provide the correct medication, the proper dose, or accurate directions for use.[20] Three theories have generally been relied on to relieve pharmacists of a duty to warn:

1) it would interfere with the doctor-patient relationship,
2) it would violate the learned intermediary doctrine, and/or
3) it would contradict public policy.[21]

Recently pharmacists as a professional group have been expanding their role well beyond that of prescription fulfillment to play a more active role in the healthcare delivery system. This new vision of "pharmaceutical care" transforms the pharmacist into a caregiver who provides patient education, monitoring, and adverse event reporting[22]. Through these changes in the professional paradigm, pharmacists are creating a new standard of care, one that incorporates a responsibility to warn patients. As noted by Myhra, of Texas Tech University School of Law:

> Today's pharmacy education, in contrast, is patient oriented. Pharmacists receive five or more years of education and training, during which they learn, among other things, how to interact with patients and physicians and how to provide information and warnings to patients. In short, pharmacy schools emphasize the necessity for pharmacists to take active roles in the provision of patient health care and, importantly, in the counseling of patients about prescription medications and potential problems such as adverse interactions and side effects.[23]

Most courts addressing the pharmacists' potential duty to warn have not addressed this shift in the profession. However, courts in several jurisdictions have noted this change and in so doing have found a duty to warn. These courts have acknowledged the expertise of the pharmacist and the potential for improved therapeutic outcomes if

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[20] See R. Paul Asbury, "Pharmacist Liability: The Doors of Litigation Are Opening," *Santa Clara L. Rev.* 907 (2000). P. 40
[21] See Jennifer L. Smith, "Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacists' Expanding Liability and Duty to Warn," *Hous. J. Health L. & Pol'y* 187 (2002). P. 2
[22] See Alison G. Myhra, "The Pharmacist's Duty to Warn in Texas," Rev. litig. 27 (1999). P. 18
[23] See id. at 60.

this duty is imposed.[24] To some extent the courts may also be reacting to Congressional requirements that pharmacists expand their role and deliver more direct care.[25]

When patients face the task of deciding whether or not to take a medication that has been prescribed for them, they need to balance the potential benefits of the drug against the risk of side effects and the seriousness of the side effects. To do this they need information that does not exaggerate either side of that equation. One would expect that this environment of expanding liability would inhibit candor by pharmacists in that it likely would cause them to overemphasize the risks and seriousness of the side effects. In fact, two in five (39%) pharmacists surveyed in the Harris PHRM poll indicated that they often over-emphasize the possible side effects of prescription drugs to patients. One in ten (10%) does this very often. Half of pharmacists (51%) believe the information given to patients in the patient packet insert is too complicated and that product liability is central to making it complex. So, patients appear to be getting overly complicated information in the package inserts, and then too often they get information from pharmacists who overemphasize the risks.

As is the case with physicians, pharmacists reported instances when patients have stopped taking medication or refused medication that was properly prescribed because of awareness the medication was the subject of litigation. Over two in five (44%) pharmacists report that some of their patients have stopped taking medication that was properly prescribed for them because they found out the drug might be involved in product liability litigation. Two in five (40%) pharmacists also report that patients have refused to take a properly prescribed drug because the patient knew the medication was involved in product liability litigation.

The Impact of Pharmaceutical Liability on Patients

It has already been noted that the fear of liability may have an adverse effect on patients in several respects:

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[24] See id. at 71.

[25] The Omnibus Budget Reconciliation Act of 1990 (OBRA) requires states to implement "drug use review' programs to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse events. It requires, among other things, that pharmacists offer to discuss with patients, in detail,

- The financial costs of defensive medicine are high and passed through to patients.
- Unnecessary tests or procedures that are not medically necessary but are ordered as a protection against liability impose risks and discomfort on patients.
- Doctors prescribe more medications than are needed, putting patients unnecessarily at risk of side effects.[26]
- Patient packet inserts are more complicated than they need to be due to the influence of liability, interfering with the ability of patients to get meaningful information about risks and possible side effects.
- Physicians sometimes avoid prescribing appropriate medications because of litigation fears.
- Pharmacists sometimes over-emphasize the risks and seriousness of side effects because of liability fears.
- Both physicians and pharmacists report that they are aware of patients who refused to take a medication, or discontinued taking a medication, because of litigation involving the drug.

Harris also went to the patients themselves to supplement this information. In the interest of interviewing people who were currently under medical care, the interviewees were randomly selected from lists of patients with at least one of eight medical problems: high cholesterol, hypertension, arthritis, depression, obesity, diabetes, heart disease, or stomach ulcers. The patients were asked about their awareness of product liability litigation involving specific drugs. As testament to the ubiquity of trial lawyer advertising to solicit clients for pharmaceutical product liability actions, most patients (86%) are aware of advertisements run by law firms about product liability suits over a specific drug. One in five (21%) have seen an advertisement for litigation over a drug they were taking.

Patients react to such advertisements with concern. Nearly nine in ten (86%) of the patients would be concerned if they saw an advertisement regarding litigation over a drug they were taking. Half (50%) would be very concerned. The patients were asked what actions they would take as a result of seeing such litigation ads. The results were as follows:

- Would call their doctor: 90% yes, 6% no, 4% not sure;
- Would stop taking the drug immediately: 25% yes, 44% no, 31% not sure;
- Would call the law firm mentioned in the ad: 19% yes, 47% no, 34% not sure.

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facts about the use of medications, including "side effects, adverse effects, adverse interactions, or contraindications."

[26] In addition, the excessive prescribing of antibiotics has contributed to a reduction in their efficacy.

Less than one in ten (8%) have ever had to do any of these. This is inconsistent with the findings discussed above: one in five has seen a litigation-related ad for a drug he/she was actually taking, nine in ten would react to such an ad with concern, and nine in ten would call their doctors. Since the people who were interviewed were in the continuing care of their doctors, it is possible that the need to call their doctors was obviated by regular visits at which time the medication could be discussed.

The majority of patients (69%) also express concern if a packet insert warns of possible serious side effects, with one in five (20%) patients not taking a drug prescribed by his/her doctor as a result of reading information about possible serious sides effects provided by the patient packet insert. This information about patient noncompliance underscores the need to have packet inserts communicate side effects and risks in a way that is clear and meaningful to patients, not in complicated legalese as is often the case.

Although patients would be alarmed by news that a drug they were taking was the object of litigation, patient responses to questions about whether or not such litigation is likely to be meritorious reveal a cynicism about the litigation. Most patients (72%) believe that it is common for law firms to file product liability lawsuits against drug companies when only a small number of people have experienced side effects from a drug. Two in five (41%) think it is *very* common for law firms to do this. Although few patients (27%) say they would join a lawsuit over a drug if they had not experienced side effects, the majority (86%) thinks that it is common for other people to join these lawsuits. Two in five (43%) believe it is very common for people to join a lawsuit over a drug they were taking, even if they had not experienced any side effects from the drug.

Patients have a striking awareness of the possible overdeterrence effect of product liability litigation. The majority of patients (71%) feel that product liability litigation, or the fear of litigation, has likely caused pharmaceutical companies to avoid research in certain product areas. Over a third (35%) say it is very likely that companies have avoided research because they fear groundless product liability litigation. Four in five (80%) patients are concerned that groundless product liability litigation prevents pharmaceutical companies from developing new and beneficial drugs. Nearly half (44%) say they are very concerned this may be occurring.

There is independent evidence that their concerns are founded in fact. Below are some examples:

A Conference Board survey of corporate CEOs, across many industries including pharmaceuticals, revealed that 36% had been prompted to discontinue products because of litigation, and 30% had decided against introducing a new product because of litigation concerns.[27]

In the early 1990s liability against vaccine manufacturers drove many from the market. For some vaccines, only a single supplier existed in 1994. For one manufacturer a single punitive damage claim totaled more than 200 times the annual revenue generated by the vaccine.[28]

Steven Garber of RAND has developed a simulation model based on how R&D decisions get made in pharmaceutical companies. It's based on an investment model that looks at future profit flows and discounts them to present value, factoring in product liability risks above and beyond typical risks for a typical product. Garber uses the model to illustrate how incremental increases in the discount rate caused by projected increases in product liability risks can significantly affect a company's R&D decisions such as whether to initiate clinical trials. He notes that "product liability risks can have a very real, a very very large effect on incentives to innovate."[29]

Finally, the likely impact of significant tort liability in the biotechnology industry is particularly poignant, in light of the role that industry plays in pharmaceutical innovation. To quote Burk, George Mason Law School, and Boczar, McCutchen, Doyle, Brown, and Enersen:

> The possibility of overdeterrence in the biotechnology industry is heightened by additional factors related to the structure of the industry. Dedicated biotechnology companies tend to be small, entrepreneurial, and focused on a single product. Any shadow on a small company's single product is likely to portend the end of that company. This is what occurred, for example, in the case of Cetus Corporation. Although Cetus was considered a large and relatively strong DBC, postponement of FDA approval for its flagship product,

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[27] See Schwartz, supra note 5, at 1010.

[28] See Gregory C. Jackson, M.D. "Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation," Am. U. L. Rev. 199 (1992). P. 42. In response to this crisis the Congress passed into law a federally administered compensation system for vaccine claimants.

[29] See Garber supra note 8 at 14.

> Interleukein-2, contributed to the company's dissolution. A court injunction or major damage award could lead to the same result for many biotech companies, and even a single such incident could well discourage the capital investments that have been required either to start new DBCs or to sustain those already in existence.[30]

Conclusion

Using a Harris poll of doctors, pharmacists, and patients to inquire about the impact of liability on pharmaceutical prescribing, warning, and compliance adds force to the existing evidence that the tort liability system creates overdeterrent effects. The impact on patients may be significant: doctors may avoid the best prescription because of liability fears; pharmacists may overemphasize the risks and frighten patients into not taking it; patients may learn of litigation involving the drug and not begin the medication or stop taking medication they are currently on; and pharmaceutical companies may fail to develop or to bring to market new medications out of fear that they will become targets of unfounded litigation. More research is needed to clarify how frequently this occurs and to what effect. It is likely that much of this overdeterrence is fueled by the unpredictability of the tort system, which fails to set up clear rules or standards *ex ante* so that doctors and pharmacists can assess which behaviors will expose them to liability and which will protect them from liability. Personal injury litigation involving a specific drug also frequently sends inaccurate signals to patients that a drug may have risks that go beyond what they were told by their physician or pharmacist. Reforms that reduce the unpredictability in the pharmaceutical liability system would go a long way toward protecting the well being of patients.

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[30] See Burk and Goczar supra note 7 at 830.