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1	IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS
2	EASTERN DIVISION
3	WENDY B. DOLIN Individually and as) Independent Executor of the Estate of) No. 12 CV 6403
4	STEWART DOLIN, deceased,
5	Plaintiff,
6	vs. Chicago, Illinois
7	SMITHKLINE BEECHAM CORPORATION) D/B/A GLAXOSMITHKLINE, a Pennsylvania)
8	Corporation,
9	Defendant.) 9:220 o'clock a.m.
10	VOLUME 20 A
11	TRANSCRIPT OF PROCEEDINGS BEFORE THE HONORABLE WILLIAM T. HART
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1 (The following proceedings were had in the 2 3 presence of the jury in open court:) 4 THE COURT: All right. Thank you very much, ladies 5 and gentlemen. Please be seated. And we will proceed. 10:10:03 6 Ladies and gentlemen, at this time you have now heard 7 the evidence in the case and it is the right and duty of the 8 lawyers to present final arguments to you. Let me tell you about today and how it will progress. 9 10 The plaintiff goes first in recognition of the fact that the 10:10:22 11 plaintiff has the burden of proof in the case. Then the 12 defendant is allowed to answer the plaintiff's argument. And then finally, the plaintiff makes a short final argument in the 13 14 After that, then I'll instruct you on the law, and I'll case. 15 give each of you a copy of the jury instructions. It will be 10:10:42 16 your copy. You can take it to the jury room. You can write on 17 it and pay attention to it as you will during the course of 18 vour discussions. After I give you the instructions, then the case will 19 be in your hands, and it will be submitted to you for a 20 10:10:57 21 decision. 22 And today it'll take about 4 hours. I've allowed the 23

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24 They may think it's quite enough to quit before the time 25 allowed, but that's approximately. So today is the final

parties each 2 hours to argue. They may not use that time.

10:11:15

		opening argument - by Rapoport 4267
	1	
	-	arguments and today is the day in which you will instructed on
	2	the law and you'll get the case.
	3	You may proceed.
	4	MR. RAPOPORT: Thank you very much, Your Honor. May
10:11:27	5	it please the Court. Ladies and gentlemen, family members and
	6	counsel.
	7	OPENING ARGUMENT ON BEHALF OF PLAINTIFF
	8	MR. RAPAPORT: We welcome you as fellow officers of
	9	the court. And I want to start by thanking you for your time
10:11:46	10	and attention. I know it's not easy to leave your lives and to
	11	come here and judge something like this over a long period of
	12	time, but we're getting close to the end. So for that, I'm
	13	sure we're all grateful.
	14	In my comments this morning I'm going to utilize the
10:12:06	15	help of a PowerPoint presentation and some other things that we
	16	have laying around to try and make this case as clear and easy
	17	to understand as possible.
	18	So, let's begin. There are three jobs that you have,
	19	one of them is to decide the facts, apply the law to the facts
10:12:29	20	and answer the verdict questions. And pretty soon you'll find
	21	out what those questions are.
	22	The second job is to make sure that every one on the
	23	jury carefully follows the law that you will be given.
	24	And the third job is to explain to each other why you
10:12:45	25	feel the way you do about each question in your deliberation.

opening argument - by Rapoport

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1 So, today we have a new puzzle piece, the law. And 2 the way that this works is, His Honor worked very hard to put 3 together the law that governs the case and has let us know what 4 the law is. 5 So, I'm freer at this point in the proceedings than 10:13:05 6 ever before to talk with you. You know, you've sort of seen 7 how the trial works. There's jury selections, there's rules 8 that govern everything. The rules are freest at this moment because you've heard all of the evidence. You know the 9 10 evidence as well as anybody. You haven't yet heard the law. 10:13:26 11 And the reason that the Court let's us know what the law will 12 be is so that we can talk with you about that. 13 So it's a new puzzle piece and it's something that I'm 14 going to spend a little bit of time talking about this morning, 15 but before doing that here is what the verdict form will look 10:13:44 16 like. It'll be on white paper. I actually have a copy of it 17 here. 18 (Brief pause). 19 MR. RAPOPORT: So, the real deal looks more like this 20 (indicating). But what you have is Roman Numeral 1, it says 10:14:01 "liability," which is a fancy word for "fault" and we're going 21 22 to talk about other, you know, fancy words that the law uses. 23 But it's straight up there, "for plaintiff." The 24 plaintiff, as you know, is Wendy Dolin. You know the 25 circumstances that bring her here. So, for the plaintiff or 10:14:22

against the plaintiff, that's really the first question. Who
 wins and who does not.

3 The second question is the damages question. And you 4 can see both on the PowerPoint and here you can see that I'm 5 holding up, it's a fairly straightforward-looking form, it says "for damages, wrongful death damages," there are two different 6 7 types of damages, wrongful death damages and what are called 8 Stewart Dolin's survival damages. Then there's a place for a total if you hold in favor of Wendy Dolin, and a place for 9 everybody's signature, including one line that says "presiding 10 11 juror."

Now, what is a presiding juror? Well, there isn't really rank among jurors. You're all equal in your deliberation, but the Court will give you an instruction that explains that you should choose from among you a presiding juror that would at least lead in any communications that are necessary with the Court. You've seen this on TV. You know, there's one person that sort of speaks for you.

But your verdict, you'll see, does not have any places for dissent, and that means that the 9 of you need to agree about a unanimous verdict, and that's part of what we're doing, pat of what it's about.

23 So, this is -- on top is something that we've just 24 written. It's a kind of a formula. I'm sure you've seen 25 enough mathematical formulas in this case for a lifetime, but

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here's another one, it's facts plus law equals verdict. And I
 have a direct quote of what I believe the Court will instruct
 you about your first duty to decide the facts from the evidence
 in this case, and that's your job, and yours alone.

5 So, you know, there are 10 -- 10 neutrals in the room: 6 Presiding judge, who, of course, is a neutral that's here to 7 fairly preside over a trial, make sure that everybody gets to 8 be heard in a civilized way, and that the rules of evidence are followed in the rules of law, and the group of you. You're 9 10 independent people doing this judging function, but the judge 11 is telling you, and will tell you after these closing 12 statements are over, that you are really the ones who decide the facts. 13

On the other hand, the second duty is to apply the law
that the Court gives you to those facts, and on that issue the
Court is the one that makes the determinations and the jurors'
job is to follow the law as given. So, that's just some basics
to get us going.

Well, what am I going to do with the time allotted here? First of all, I'll do my best not to use all of it. I can't make a promise there, but I'm going to try my best not to maybe use every single second. We are going to talk about the law, which we've already started, and then I'm going to talk about the facts in this case and the legal conclusions that are supported by the evidence in this case.

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	1	So, what is evidence? We're going to talk about law,
	2	we'll cut through this fairly quickly, but what is evidence?
	3	So, it consists of witnesses and the testimony of witnesses,
	4	whether they're on the witness stand or on video, or exhibits
10:17:55	5	that have been received into evidence by the Court, that is
	6	what evidence is.
	7	You'll see some words, or you have heard some, I think
	8	His Honor mentioned "burden of proof," and clearly the burden
	9	of proof rests with us right here at this table, the people
10:18:15	10	that are prosecuting this case.
	11	And so what is our burden of proof? Well, it's not to
	12	prove we're not required to prove anything beyond every
	13	reasonable doubt. You hear that on television sometimes, but
	14	this is a lawsuit for money damages, and it's governed by a
10:18:32	15	different and lower legal standard. It's governed by tipping
	16	the scales just a little bit.
	17	And so the precise language is right here
	18	(indicating). You can see:
	19	" in a civil action, such as this one, the
10:18:47	20	burden is on the plaintiff to prove every
	21	essential element of each claim " and we'll
	22	look at all of those " by a preponderance of
	23	the evidence.
	24	Now, that's a funny term, but it's defined, it's
10:18:56	25	defined and. You'll see when you get the instructions, a lot

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1 of times terms are defined in them.

So a preponderance of the evidence means that you must be persuaded by considering all the evidence that something is more probably true than not true. And the little drawing there is showing that. It means a 51 percent probability, not a 99.9 percent probability, or anything like that. So what is the burden of proof is important.

8 And when we get to that, the bottom line is the burden 9 of proof is more probably true than not true, and it is a 10 violation of the law for anyone to require more.

11 So, for example, you could be back there and you'll be 12 in a discussion, you've got the law right there, you know you 13 have to follow it, and, you know, most of you may have a point 14 of view, and then somebody says, "well, no, but this hasn't 15 been proved to 100 percent certainty" and the answer to that 16 is, that's not the law. It's more probably true than not true, 17 so that's how it works.

Now, what is a proof of what? Okay. That's kind of a
reasonable question. Now we talked about the standard, well,
prove what? So, we claim that GSK committed something called
"negligence." That's not really a word of common usage, and so
in a minute, when we get to the next board, I'll show you what
the definition of "negligence" is under law as Judge Hart has
ruled. So, committed negligence:

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"... to succeed on this claim the plaintiff must

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		opening argument - by Rapoport 4273
	1	prove each of the following propositions by a
	2	preponderance of the evidence."
	3	And this is right out of the instructions. I'm not
	4	going to read you every single instruction that the Court has,
10:20:46	5	but I'm highlighting the ones that are really at the heart of
	6	this.
	7	Number 1:
	8	" GSK negligently engaged in one or more of
	9	the acts claimed."
10:20:56	10	And in a little while you'll see the acts
	11	claim.
	12	Number two:
	13	"One or more of those acts was fault or was
	14	negligence."
10:21:04	15	And number 3:
	16	" GSK's negligence was a proximate cause of
	17	Stewart Dolin's emotional distress, suicidal
	18	behavior, and consequent death."
	19	So, those are bunch of words and we sort of need to
10:21:17	20	dig into those words a little bit just to understand them a
	21	little deeper so that nobody things, for example, that
	22	negligence means intent to harm.
	23	If anybody back there were to say, "I can't rule in
	24	favor of Wendy Dolin in this case because GSK didn't have any
10:21:36	25	intent to harm" you should answer, "no, that's not the law" and

		opening argument - by Rapoport 4274
	1	"no, that's not required. Intent of harm has nothing to do
	2	with this."
	3	So, what does the law say? Well, we're talking about:
	4	" it's the duty of everyone, human or
10:21:50	5	corporation, to"
	6	Excuse me:
	7	" doing something which a reasonable careful
	8	person would not"
	9	Oh, there it is. I started in the wrong place.
10:22:06	10	Can't read my own red writing: What is fault, what is
	11	negligence:
	12	"Failure to do something which a reasonable
	13	careful person or corporation would do or doing
	14	something which a reasonably careful person or
10:22:20	15	corporation would not do under circumstances
	16	similar to those shown by the evidence."
	17	The law doesn't say how a reasonably careful person
	18	or corporation should act, that's for you to decide.
	19	So, this concept, when you hear "negligence," it's not
10:22:38	20	evil, it's fault. It can be as simple as a mistake. It is not
	21	the plaintiff's burden to prove evil conduct here.
	22	Some of you may believe that evil conduct occurred,
	23	and you'll hear from me, I know you know about what we make of
	24	the conduct that we've seen that contributed to cause this
10:22:58	25	death, but the bottom line is, what is it that is required?

	1	Simple fault. The doing of something that you shouldn't do or
	2	the failing to do something that you should.
	3	When you think of the word "negligence" and if
	4	somebody back there is arguing, "no, negligence doesn't mean
10:23:14	5	that, it means something enhanced," the answer is, no, it's
	6	simple fault. It's doing something that you shouldn't do or is
	7	nailing to do something that you should in the eyes of the
	8	jury.
	9	Now, this cause thing, "proximate cause," the only
10:23:33	10	time I ever heard anybody use a phrase like that was when I
	11	started learning this legal mumbo jumbo back in the late 1970's
	12	and '80s. In conversation what says, what's this? Oh, it's
	13	the approximate cause of that." So oops, let me get back to
	14	where that was.
10:23:56	15	So, what's it mean? Well, it's a specifically defined
	16	term and here is what the court is going to explain what that
	17	term means:
	18	" as used in these instructions, proximate
	19	cause means a cause that, in the natural or
10:24:07	20	ordinary course of events, produced the death of
	21	Stewart Dolin. It need not be the only cause,
	22	nor the last, nor the nearest or last cause. It
	23	is sufficient if it combines with another cause
	24	resulting in Stewart Dolin's death."
10:24:24	25	Now, let's talk about that just for 30 seconds or so.

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1 It doesn't say proximate cause means -- first of all, it doesn't say "the cause." Now, this is important because 2 3 sometimes a simple thing like "the" versus "a" is the 4 difference between an important idea like "the only cause" 5 versus one of many cases. Do you see what I mean? 10:24:50 6 So, our burden in this case is to prove that the fault 7 of GSK was one cause of Stewart's death, not the only cause, 8 not the last or nearest cause. It's sufficient if it combines 9 with another cause resulting in the death, that's the 10 principle. 10:25:14 11 And somebody back there may argue, "well, we can't 12 hold for Wendy Dolin because Wendy Dolin didn't prove that what 13 they did was the only cause of Stewart Dolin's death," and the 14 rest of you need to answer, that's not the law. That would 15 violate our second duty. We have to follow the law and the law 10:25:30 16 is the law of one cause, it's not the law of the only cause. 17 All right. Now, what is the duty or yardstick of a 18 pharmaceutical company like GSK when it comes to what do they 19 have to do. What are the dos and don'ts of a pharmaceutical 20 company. 10:25:55 21 Well, the Court explains it in this important instruction, and I'm going to read this one straight up: 22 23 "Defendant is responsible for the conduct -- for 24 the content --" let me start again: 25 "Defendant is responsible for the content of 10:26:07

1 the paroxetine label at all times. It is 2 charged both with crafting an adequate label and 3 with ensuring that its warnings remain adequate 4 as long as the drug is on the market. Under FDA 5 regulations, defendant is required to revise and 6 update its label to include a warning as soon as 7 there is reasonable evidence of an association 8 of a serious hazard with the drug; a causal relationship need not have been proved." 9 10 that is the law of the obligation. 10:26:46

> 11 So examples of applying this law would be it was GSK's 12 label, it was GSK's obligation to be truthful to doctors about 13 the dangers and the possible dangers that it either knew or 14 should have known about. That was its job, that was its duty. 15 This instruction does not say the FDA is the one that is in 16 charge of the label. It says that the defendant is responsible 17 for the content of the paroxetine label at all times.

> 18 When you take this in combination with the instruction about one cause, somebody back there may say, "I can't hold for 19 Wendy Dolin because I think this is the FDA's fault," but the 20 21 answer is even if the FDA were partially at fault, that's not a 22 defense because that would be only one contributing factor, and 23 the law says that it was the defendant that was responsible for 24 the paroxetine label at all times, at every time.

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All right. Now, I'm going to spend a couple of

1 minutes talking about the law of damages, because this is 2 something that people are curious about, because we believe, 3 based on the evidence and on the law, that you will end up 4 deliberating on damages. And, of course, before I finish my 5 closing statements I'm going to explain in clear terms what the law is and what we believe the evidence has shown and what we 6 7 believe is an appropriate award of damages under the law.

8 So what is the law of damages? Well, here you can see the instruction that I have before you that describes two 9 10 general types of damages, wrongful death loss and survival 11 loss. And so that we have -- I'm not going the read that entire thing, but that's kind of an introduction to the damages 12 13 and I want to dig in deeper.

14 So, when we start talking about the wrongful death 15 damages, we have three guick boards to show about that. If vou 16 decide for Wendy Dolin on the question of liability, you must 17 fix the amount of money which will reasonably fairly compensate 18 the widow and adult children for Stewart Dolin for the pecuniary loss, that's another defined term, proved by the 19 evidence to have been proximately caused by Stewart Dolin's 20 21 death:

> "Wrongful death damages may include loss of money, benefits, goods, services, and society."

And this word "society," this is a non-money loss. 25 This describes the mutual benefits that each family member

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receives from the other's continued existence, including love,
 affection, care, attention, companionship, comfort, guidance
 and protection. There aren't too many phrases in the law that
 are a little bit poetic, but this is one of them, and this is
 talking about the human losses when a person passes away.

Here's the third piece, which is a very detailed
instruction, and you'll hear all about it, you'll hear more
from me about it later, but it's describing the many different
things that come into play when somebody is deliberating over
wrongful death damages.

11 So, you can see up top, it's "money, benefit, goods, 12 and services," and "society," as we mentioned before, and it 13 goes on to describe all the many things about a person's age, 14 their general health, their marital status, their past 15 productivity, and all the other things that you see, sobriety and thrift, and occupational ability, habits of industry. You 16 17 see so many things on there, and you'll get a chance to see 18 that in more detail.

19 So I'll just keep us moving here. So, the keywords 20 there, you'll see when I go back to it, "reasonably and fairly 21 compensate" was kind of the start. "Reasonably and fairly 22 compensate" you see it right there (indicating), and what we 23 get on that is, "to reasonably and fairly compensate." And 24 this is a scaled kind of situation going on. And I use the 25 Lady of Justice occasionally through closing statement like

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1 this because there are reminders almost everywhere on the Lady 2 of Justice about important things associated with our system. 3 So, for example, the blind fold, which I think we all 4 understand, means equal justice for everybody under the law. 5 And the scales are a balancing process that comes into play. The sword is recognizing the power of Lady Justice, which is, 6 7 of course, a very direct reference, as well, to the power of 8 jurors, and to the power of a jury box, one of the greatest 9 freedoms that we have.

So, this balance I want to talk about for a minute,
because "compensate" is another one of those words.

12 "Compensate" doesn't mean reward, it doesn't mean pay-off, it's
13 not a lottery, it's nothing like that. "Compensate" in this
14 sense is, again, about the balance. It's about weighing things
15 equally.

16 I think we all understand this in general terms with 17 work. We give the work and we get compensated. We get paid 18 for the value of the work or maybe, you know, we don't all get 19 paid what we hope for the value of the work, but the idea, the 20 basic agreement is, you know, the people that are paying for 21 the work have to pay for the work, that's done, that's 22 compensating. The work has value and the money equalling the 23 value is what goes on the other side.

24 Same thing here. So when we do the damages, we're 25 doing a weighing process, but the only weighing is what is the

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1 harm and what is the amount of money that is -- that can offset2 that harm, that's the law.

3 Here's the law of Stewart Dolin's damages, survival or 4 Stewart's damages. So, what this explains is that if you 5 decide for the plaintiff on the question of liability, you must 6 fix the amount which will reasonably and fairly compensate the 7 estate of Stewart Dolin for any of the following elements 8 proved by the damages, survival damages, which cover the period 9 from July 10th until his death or on July 15th, and those 10 issues are emotional distress, pain, and suffering, and loss of 11 a normal life. So these are things that we'll talk about 12 later.

Okay. So, that completes the first segment of what I
had hoped to comment about, and this enters the second segment,
which is what facts and legal conclusions are supported by the
evidence in this case. So, now you've had introduction to the
law, let's take a look at the evidence and see what's what.

18 So obviously, you know who we're suing. And you 19 probably have a pretty good sense now for why, but here we're 20 making a clear statement that the company, with fault, 21 negligently, violated the legal duty it owed by, number one, crafting an inaccurate label in the first place. 22 Number two, 23 not ensuring that its warnings were accurate over time. Number 24 three, not revising its label to include a warning about the 25 association between suicidal behavior and Paxil for adults over

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	1	24 before Dr. Sachman prescribed the drug for Mr. Dolin on
	2	June 28th of 2010. And I'm sure you all remember Dr. Sachman
	3	from the day that he testified. And as a close friend of the
	4	Dolins, along with the Dolin family, he is here today as well.
10:35:12	5	Now, here are you'll get in the instructions, and I
	6	think when the Court gives you these first of all, they're
	7	not that thick a stack, and, secondly, I think he's going to
	8	give you a nice index on the front so you can find topics
	9	really quick, and one of the topics will be the contentions of
10:35:35	10	the parties, or something like that. And so in legal terms,
	11	what you will see in the lawsuit and what you will see in the
	12	instructions are these four listed claims that GSK provided
	13	number one that:
	14	" GSK provided an inaccurate warning label
10:35:52	15	for paroxetine that hid the risk of
	16	paroxetine-induced suicidal behavior for persons
	17	over 24 years of age.
	18	Number two, that GSK included in the paroxetine
	19	label a misleading statement concerning suicide
10:36:05	20	for persons over the age of 24.
	21	Number three, that GSK provided the FDA with
	22	inaccurate data relating to suicide for persons
	23	over 24, or"
	24	and you'll notice that that "or" is in green, that's
10:36:22	25	for a reason:

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"... or GSK withheld from the FDA significant
 data concerning suicide relating to suicide for
 persons over 24 years of age."

So why is the little "or" green? The little "or" is green because it's another one of these things, like we talked about "a cause" meaning one cause, not the only cause, it's the same kind of thing here. So, if we've proved any one of these things, then that is enough to relieve us of any further burden of proving, because it's basically 1 or 2 or 3 or 4.

10 Now, we believe that the evidence strongly supports 11 proof of all four of these things, but one is what it's about. It does not require all four and you need to understand that. 12 So if somebody back there argues, "can't go for Wendy Dolin 13 14 because they didn't prove all four," the answer is the law 15 doesn't say that. That law says they only have to prove one; 16 more probably true than not true, 51 percent probability, one 17 of those things.

Now, what's the defense position? It's kind of the
exact opposite. I think you've seen from the start this game
of opposites that we and they seem to play. The defense denies
that it engaged in any of the acts that I just mentioned, and
contends that, and they've got their four things:

23 Paroxetine doesn't induce suicide in people over 24,24 is their first argument.

And their second one is, GSK provided accurate,

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non-misleading label information to doctors about the risk of
 suicide with people over 24, and Dr. Sachman was aware of that
 risk when he prescribed the drug for Stewart number.

Number three, that GSK didn't mislead the FDA when it
provided the agency with data relating to suicide for people
over 24 years of age.

And number four, that GSK did not withhold information from the FDA about suicide in people over 24 years of age.

9 Okay. So, that kind of puts on the table what is the 10 law, the new puzzle piece, what's to fight, okay.

So, the next part is, what's our fight. And I see that Mr. Sims is in motion, and while he's doing that it's the opportunity to thank our great team members, Sims, and, of course, Brent Wisner, and the many other folks that you've met from our team.

So, as we start the process of digging into the evidence in this case, you have before you what I think is a quick summary of the bottom line. As complicated as this case has been, and as long as we've sat here, at the end of the day this green and red arrow tell the story.

The green arrow tells the story of what should have happened, which is from the very beginning, before this drug came out in the first place, GSK discovered risks in the clinical trials of suicide that should have been revealed to the FDA and doctors in the form of a warning from day one.

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Now, I'm going to do something, I'm going to have Mr.

And if there had been a drug causes suicide or is
 associated with suicide warning on that label from day one, Dr.
 Sachman would have never prescribed paroxetine for Stewart
 Dolin, and Stewart Dolin would be here today instead of where
 he is.

So, what happened instead? Suicide risks discovered in clinical trials were not revealed to the FDA and doctors, That label has never had -- I data was misrepresented. shouldn't say "never." We'll get to that part, but that label has largely not had any warning at all about the association 11 between that drug and the suicidal behavior risk for people 12 over 24. And for about half of its life, the period of time shown on these arrows, that drug didn't have suicide associated 13 14 with the drug warning for anybody. And we'll get into all of 15 this in more detail, because you heard some evidence, some of 16 it is easy to understand, some of it a little less so, but the 17 bottom line is what we put on the black strip down there:

18 1989 GSK submitted a New Drug Application for Paxil, 19 paroxetine, which obscured an approximately 8-fold increased 20 risk of suicidal attempts and suicide through improper use of 2 21 run-in suicides and 5 run-in suicide attempts. This changed 22 the danger signal to a reassuring one. As a result, doctors 23 and the FDA were not warned about the increased risk that GSK 24 knew or should have known about at the time.

1 Sims do something now that is a little bit symbolic, which is 2 I'm going to ask him to walk that green and red arrow up to 3 that witness chair, and take that thing in so that it can stay 4 with us for the remainder of the trial. And while he does that 5 I'm going to tell you why I'm having him do something that strange, because I'm handicapped in this case. We've done our 6 7 best to present the evidence to you in a reasonable way and 8 from our hearts, but there are things that we can't do. We're handicapped because we can't bring Mr. Dolin back and have him 9 10 explain his side of this.

11 Now, we've had to sit here with patience and listen to 12 people like Dr. Rothschild and others by defense team who 13 sometimes just make things up about what Mr. Dolin's last day 14 consisted of or last few days consisted of. And I only wish 15 that I had a witness, and I wonder what my witness may have 16 said if he could have given his side of the story instead of 17 these hired people telling various sides of the story. So, 18 that's my witness, ladies and gentlemen (indicating), and those 19 arrows are going to sit here from that witness chair for the remainder of my comments, and when I come back at the end for 20 21 final comments I will bring that back as well.

23 So, the next thing is -- I say "poor," in part, 24 because of what you're watching and, in part, because what I'm 25 going to do to him next. So, what I'm going to do to him next

And while -- poor Mr. Sims.

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		opening argument - by Rapoport 4287
	1	is, we have a timeline put together that great. Ms. Reed is
	2	in play. Thank you very much.
	3	So, what they're putting up is a timeline that pulls
	4	together the story of GSK's conduct in this case in a little
10:43:58	5	more detail.
	6	Now, there you have the timeframe, and I have an
	7	electronic version of this as well. And actually, I was
	8	thinking that I probably should take the tethered microphone
	9	out which we may have.
10:44:18	10	(Brief pause).
	11	MR. RAPOPORT: If I get this device going I'll walk
	12	over there and it'll be better, and, if not, we'll do it
	13	another way.
	14	(Brief pause).
10:44:45	15	MR. RAPOPORT: There's also the laser beam on. Sorry
	16	to crank anybody's head, but my eyesight is only so good.
	17	So, let's walk through this and we'll try to do it a
	18	little quick.
	19	So 1989, what happened?
10:45:05	20	" GSK submitted a New Drug Application to the
	21	FDA for Paxil which obscured approximately
	22	8-fold risk of suicidal attempts and suicide
	23	through improper use of the two run-ins."
	24	That I already mentioned, and I think you remember
10:45:19	25	that story. I'm going to show you more about the story, but

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they changed the danger signal into a reassuring one, and, as a
 result, doctors and the FDA were not warned about the increased
 risk of suicidal behavior that GSK knew or should have known
 about from the very start.

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5 But what happens after that this? We have on 6 October 3rd of, I believe, 1990, the FDA requested a report 7 from GSK on the same suicide issues that were raised in the Teicher article about Prozac. And you might remember this 8 story, that Teicher and the very famous Dr. Cole that he worked 9 10 with had 6 patients who did violent -- had violent suicidal 11 attempts while they were on Prozac. It was a new drug and in a class of drugs, got a lot of attention. 12

So, at this point GSK came under some pressure
inquiry. And what happens after that? Under increased
scrutiny on the suicidality issue from the FDA, GSK's director
of regulatory affairs inaccurately informed the FDA, quote:

"... analysis of data from prospective clinical trials in depressed patients clearly demonstrates that patients randomized paroxetine therapy were at no greater risk for suicidal ideation or behavior than patients who were randomized to placebo; however, the hidden data revealed the opposite was true, there was an approximately an eight-fold increased risk of suicidal attempts and suicides from their

		opening argument - by Rapoport 4289
	1	clinical trials in this drug."
	2	So what happened? In December, on behalf of GSK,
	3	doctors Dunner and Dunbar gave a presentation at the American
	4	College of Neuropsychopharmacology in San Juan inaccurately
10:47:13	5	stating that the clinical trial data for Paxil shows, quote:
	6	" suicides and suicide attempts occurred less
	7	frequently with paroxetine than with either
	8	placebo or active controls."
	9	Now, I'm sure that you remember that they had 42
10:47:30	10	attempts in the 1989 papers of suicide in the clinical trials
	11	on paroxetine compared to 1 in placebo, and they had the 5
	12	suicides compared to none in the placebo, and this is what the
	13	basis is for the strong signal, a strong signal that was
	14	deep-sixth or perhaps it was a mistake. That's one of the
10:47:55	15	things that you might be deliberating over, and I'm going to
	16	have more to say about whether it's a mistake or whether it was
	17	on purpose, except I want to point out that even though you
	18	know what I'm going to argue on that point, it doesn't make any
	19	difference because nothing more than a mistake is required by
10:48:12	20	what we have to show in this case.
	21	So bear in mind if somebody back there says, "I can't
	22	vote for Wendy Dolin because they didn't do it on purpose," you
	23	answer the law doesn't require anybody to do anything on
	24	purpose. They probably did some very bad things on purpose,
10:48:30	25	but we're not required to prove that.

1 All right. Now, 1992, relying on these inaccurate 2 representations is true. The FDA approved Paxil for marketing 3 in the U.S. and adopting as part of its summary basis for 4 approval the very inaccurate table that GSK wrote for them 5 showing that there was no increased risk when, in fact, there 10:48:50 6 was. And after that, GSK launched Paxil in the United States 7 without warning prescribing doctors of the drug's association 8 with suicide attempts and completed suicides for people of any 9 age, just left that out. 10 All right. So, we have a lot more on here on our 11 timeline. GSK instructs the sales force to distribute the Dunbar and Montgomery article to alleviate concerns about 12 13 doctors who would be prescribing this stuff, because in the 14 outer world people are hearing about suicides from this stuff 15 and doctors are wondering and they're getting reassurance from 16 Dr. Dunbar. 17 Anybody remember Dr. Dunbar? He testified on the very 18 first day of evidence. And just in case you don't, we're going 19 to bring him back pretty soon and you're going to see the

20 central part of what he had to say so you really understand 21 what we're dealing with here.

22 But, in any event, 2, 3 years in, they're pitching 23 this stuff, 1999 FDA requested death data and the GSK lawyers 24 raised concerns, quote -- right out of one their documents, 25 quote:

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".... I want to ensure our positions are not 1 2 inadvertently compromised as a result of 3 anything that we share with the FDA" 4 and they're talking about lawsuits over this already. 5 '99, GSK realizes, quote -- and every single thing 10:50:17 6 quoted here is right off of an exhibit: "... GSK realizes this response to FDA seems to 7 8 be setting us up for potential problems suggesting that Paxil is associated with a 9 10 higher rate of suicide versus placebo. Can we 10:50:33 11 use the Montgomery metaanalysis that's Dunbar 12 and Montgomery in our response back to the FDA?" 13 And check this out, they're thinking about how the FDA 14 doesn't know about these run-ins that they shoved in to mess up 15 the data. And one of their internal documents shows that they 10:50:50 16 actually asked an FDA guy in December of '99 a hypothetical 17 example about a suicide during run-in being included, and the 18 FDA person, not having any idea that this isn't a hypothetical, it's real, they just haven't told him yet, explains that such a 19 20 patient should not be counted in an analysis. And you'll see 10:51:15 21 more of these documents soon. You don't have to trust our 22 board here to back all of this up as we go along. But in '99 23 GSK submits a death report but claims it's too burdensome to 24 collect data from locally funded studies. So, this is one of 25 the many -- it's not the only game. You know, they're playing 10:51:35

games with the run-ins to flip the signal from danger to safe
 isn't the only game, that's just the first game that they
 played.

4 Over here, now, you know, things are starting to come 5 out and suicides are starting to happen in the field and lawsuits and other things, and they're like slicing -- you have 6 7 sophisticated people looking at different ways to slice the data to try to make it look like there's no signal. So, you 8 know, one of them is, just get some of the data from the double 9 10 blind placebo, not all of it, we don't want all of it, just get 11 some of it.

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12 All right. June of '01, this is a quote from GSK13 internal documents:

14"... these suicide reports seem to be appearing10:52:2315too often for comfort. This is potentially an16area which competitors are likely to capitalize17on once the lawyers have finished their work in18the courts."

April of 2002, GSK discloses run-in error for suicide attempts to the FDA, but makes an accidental misrepresentation about the two run-in suicides as if they didn't happen.

So that just -- that just covers, we know that our paroxetine prescription, and start taking it, and the death are a long way from what we've talked about already, but this first board is a mess.

		opening argument - by Rapoport	4293
	1	So where do we go from there?	
	2	" additional data collected by GSK"	
	3	this is 2002:	
	4	" revealed a continuing signal of	
10:53:13	5	substantial increased risk of suicide and	
	6	suicide attempts associated with Paxil. GSK	
	7	continued market the drug without informing	
	8	doctors of the risk."	
	9	And we get to 2005:	
10:53:24	10	" GSK added the black box warning for	
	11	suicidality in children and adolescents with	
	12	major depressive disorder noting a two-fold	
	13	increased risk for paroxetine versus placebo, no	
	14	similar warning for adults was included."	
10:53:41	15	Then we get over to 2006:	
	16	" GSK's new analysis of data revealed	
	17	"evidence of an increase in suicide attempts in	
	18	adults with major depressive disorder treated	
	19	with paroxetine compared to placebo with an odds	
10:53:54	20	ratio of 6.7 that was statistically	
	21	significant."	
	22	It's the very danger we're talking about here.	
	23	May 5th of '06:	
	24	"GSK temporarily amended the Paxil label to	
10:54:06	25	include reference to MDD clinical trial data	

	1	suggesting the higher frequency of suicidal
	2	behavior observed in the younger adult
	3	population across psychiatric disorders may
	4	extend beyond the age of 24, noting 8 of 11
10:54:24	5	suicide attempts in the clinical trials involved
	6	younger adults 18 to 30; however, this temporary
	7	and over 24 adult warning was removed from the
	8	label in August of '07."
	9	that's sort of this piece here (indicating). And
10:54:38	10	they tried to create a lot of confusion about the fact that
	11	they had the label in and it came off. And we're going to talk
	12	in detail about that when we dig in further to the detailed
	13	evidence, but bottom line is, we have this period marked in
	14	yellow. So, basically, if we want to look at when did they
10:55:00	15	have no reference at all to this drug causing you know, what
	16	I realized, and forgive me, I see other people are oops.
	17	MR. SIMS: I moved it.
	18	MR. RAPAPORT: Oh, you moved it. Thank you. Great.
	19	Okay. So, from all of this time, all of this time,
10:55:21	20	all of this time to here (indicating), there was no warning
	21	about the drug itself being associated with suicide for people
	22	and suicide attempt for people of any age. Then we get the
	23	adult piece, okay, that is not covered when they put up a black
	24	box for children and adolescents. And then we get the adult
10:55:46	25	piece up there for this little while (indicating), okay, and

		opening argument - by Rapoport 4295
	1	otherwise no, not in there, not in there.
	2	So, we get to the facts of our case here toward the
	3	end:
	4	" on June 28, 2010, relying on the 2010
10:56:07	5	version of the Paxil label, Dr. Sachman
	6	prescribed 10-milligrams per day of paroxetine
	7	for Stewart Dolin to be taken after a 10-day
	8	waiting period as Zoloft cleared Mr. Dolin's
	9	system. Dr. Sachman would not have prescribed
10:56:19	10	paroxetine for Mr. Dolin if there had been a
	11	paroxetine-induced suicide association warning
	12	for adults over 24 on the label."
	13	he testified to that clearly and unequivocally from
	14	the witness stand, you all heard it.
10:56:37	15	July 8th Dr. Sachman told Mr. Dolin he was free to
	16	start the paroxetine. And on July 10th Mr. Dolin started it.
	17	And on July 15th we all know what happened. And the way it's
	18	phrased on the board is:
	19	" Stewart Dolin's paroxetine-induced death by
10:56:53	20	train"
	21	And we'll talk much more in detail about how we know
	22	that:
	23	" as a direct and proximate result of taking
	24	paroxetine and the inadequacies in GSK's label
10:57:04	25	which did not properly inform Dr. Sachman about

opening argument - by Rapoport 4296 the risks GSK knew or should have known about 1 2 it." 3 Boom 4 So -- so, there you have a big picture timeline. 5 Now, let's go further. 10:57:21 6 This before you is -- these are the two -- they were 7 done in white during the trial. These are the two boards that 8 were shown and explained by Dr. Ross who did his calculation, 9 and this is basically the backup for the flipped signal. 10 So, what you're looking at is the difference between 10:57:43 11 when you sneak in the run-ins that didn't belong in this data, 12 the way that GSK did. Then what you can do is show that you have a lower odds ratio, and it has a P-value. I know you all 13 14 flow about P-value now. You probably never wished you heard 15 about P-value. But the short of it is that they -- they -- by 10:58:07 16 putting in the run-ins, they not only lowered the odds ratio 17 but they also create arguments that it's not a statistically 18 significant. And then you can see what the data is when it's 19 strained out. So that's why I have sponsor's, GSK's version, 20 the way they put it out to the world, and the actual is what we 10:58:26 21 showed here when you do the math the right way. Depending on which way you calculate it, you either have a 7.8 increased 22 23 risk or an 8.9 times increased risk. And these are increased 24 risks of people that are similarly situated. They're all 25 people with depression. So, it's not -- you know, the 10:58:47

arguments about, well, you know, depressed people or people
with anxiety, or whatever, have higher statistics. Well, the
whole point is that the signals are being developed by trying
to compare apples to apples. The things that they later call
apples to apples are actually apples to oranges, which I'll
explain. But, in any event, this gets us started just by a
reminder about that data that's really at the heart of this.

Now, you've heard testimony that a warning was
required from the start by at least these three doctors whose
pictures you may recognize (indicating), that being Dr. Healy,
who you saw at the beginning of the trial and again at the very
end, Dr. Ross, you saw early on in the trial, and Dr.
Glenmullen.

14 Now, going back, I'm just going to develop some of 15 this evidence, and we'll go through this fairly guickly because 16 there's a lot to show, but this is a memo on October 3rd of 17 1990 from Dr. Martin Brecher who was then a medical officer at 18 the FDA. He was in the first year of his job. He worked on 19 paroxetine. And you may or may not remember but you actually heard testimony from Dr. Brecher. He wasn't in video and he 20 21 wasn't in person, he was read by Mr. Baum, actually.

So, it happened sort of fast, but one of the reasons that we have these kind of summations at the end of a case is to come back and point out some of the things that happened. But what this memo is showing is that Dr. Brecher was

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1 connecting Prozac. We're up in that part of the timeline 2 that's upper left on this first board. And this is basically 3 the request over to GSK to give data about suicide again, and 4 in more detail, because these questions have been raised about 5 Prozac.

And here we have May of '91. And this was shown on 6 7 the board, but this is the actual document where you can see Dr. Connolly, GSK's director of regulatory affairs, state this 8 incorrect thing, quote, May 10 of '91: 9

10 "To summarize in brief, this analysis of data 11:01:04 11 from prospective clinical trials in depressed 12 patients clearly demonstrates that patients 13 randomized to paroxetine therapy were at no 14 greater risk of suicidal ideation or behavior 15 than patients who were randomized to placebo or 11:01:24 16 other active medication."

that is simply an untrue statement.

18 So, same time that statement was made, tables were put 19 up showing these run-ins. Included, you can see when you look 20 in the placebo column, you see 2 deaths included and 6 attempts 21 included, and we know that the truth is -- and you haven't 22 heard anybody deny it. You know, one thing you haven't heard 23 any one of their witnesses come in and say, oh, you know, we 24 did have 2 deaths in the placebo that weren't in the run-in. 25 Uh-uh. They don't. They don't, they can't because that had to

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1 be a zero and not a 2 and it flips the numbers around.

And, similarly, on the attempts, 6 was false, the real number was 1. And the result of correcting that table would be to give you a big giant suicide danger signal instead of the false safety signal that they claimed.

6 So, Dr. Brecher's safety review carried over what GSK 7 put up on this. So, they put up in the tables that there were 8 two placebo suicide deaths and that there were 6 attempts even 9 though that wasn't true. And I'm pretty confident that the 10 reason that that occurred is because Dr. Brecher didn't know; 11 although, we'll review that shortly.

Interestingly enough, you'll see as well, that I 12 13 highlighted "emotional lability" because they showed that 14 emotional lability was a significant problem with Paxil, they 15 just never told the FDA that what they meant by that was 16 suicides, or suicide attempts, because they were hiding it 17 under that label. And I'll have more to say about that in a 18 little while, but let's move on now to Dr. Brecher. There are 19 a couple of facts about him.

He finished his residency in '80s, spent two years only at the FDA, '90 and '91. Worked on the Paxil New Drug Application in addition to other products. He testified at his deposition, which was taken on March 13th of 2003, but read into evidence in this case, and so it is evidence here. And most importantly he testified that including

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		opening argument - by Rapoport 4300
	1	run-ins, quote:
	2	"is a scientifically illegitimate way to
	3	count."
	4	I suggest to you that when you think about it, it's
11:03:59	5	more probably true than not true that Dr. Brecher did not know
	6	GSK slipped in scientifically illegitimate run-ins in the
	7	safety review that GSK provided to the FDA, but I point out
	8	that the defense and its experts argue otherwise.
	9	There are two answers, really, to this argument. The
11:04:21	10	first answer is, it's wrong; and the second is, it wouldn't
	11	matter even if it was right. So, what do I mean it was wrong,
	12	and what do I mean it wouldn't matter even if it was right?
	13	Well, Dr. Brecher seems to have missed the run-ins
	14	even though it's in some of the fine print because the chart
11:04:46	15	that GSK gave to him didn't tell him, there was no asterisk
	16	anymore. Remember, in '89 he wasn't there when the New Drug
	17	Application was filed. And after the situation with the
	18	article and the new scrutiny, he went right back for GSK for
	19	detailed data, and when they gave him detailed data they
11:05:11	20	dropped the asterisk that used to explain that those run-ins
	21	were run-ins, and instead, didn't get into that in what they
	22	gave him. And he puts out in his safety report on this, which
	23	then becomes part of the approval on the drug, nothing in those
	24	charts that would indicate that he was aware that they had
11:05:35	25	slipped in inappropriate, scientifically inappropriate run-ins.

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1 But the defense says, it argues, you know, they have 2 another thing about that and we'll let them talk and then I may 3 come back and comment more, but why do I say it doesn't matter 4 if it was right? Well, because whether the FDA -- whether this 5 was the best day for the FDA or a bad day for the FDA really 6 has nothing to do with this, because the answer is right in the 7 jury instructions, which say that it is GSK's conduct that's on 8 trial here. The FDA is not on trial, and it's not a defense to GSK if the FDA, on a bad day, actually let themselves 9 10 accidentally get mislead or if they actually knew or were 11 complicit, Okay. None of those things are a defense in this 12 case.

13 So, here's a real quick thing that I wanted to just 14 The Court gives you some guidance about how you sort put up. 15 out conflicts between the testimony of one witness and another. 16 And this is a copy of what I believe the instruction will say. 17 And it explains a lot of different things about how to weigh 18 people's opportunity, is a witness truthful completely, are 19 they truthful in part, are they truthful not at all. These are 20 all judgments you can make and basing on the ability and 21 opportunity the witness had to see, hear, and know things, 22 their memory, whatever interest or bias they may have, their 23 intelligence, their manner while testifying, reasonableness. 24 So that's a good sort of scale. It's another one of those 25 scales that you'll find in the instructions.

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		opening argument - by Rapoport 4302
	1	So, we're about to reach another
	2	(Partial videotape deposition of Dr. Pierre
	3	Garnier played in open court.)
	4	(Brief pause)
11:10:37	5	MR. RAPOPORT: That's the CEO, at least he was at the
	6	time, the CEO of GSK. And think about this. Who called the
	7	CEO of GSK as a witness? We did. What did he say? He said
	8	that if inaccurate information was given to the FDA, that would
	9	be a pity. And he said that a suicide signal, basically at the
11:11:06	10	end, has to be revealed. He knows. He knows. We rely on the
	11	testimony of the CEO of GSK.
	12	Now, FDA inaction is no defense, I touched upon that
	13	briefly before, and here is an instruction that you will be
	14	given in this case which says, quote:
11:11:32	15	" you may consider defendant's compliance
	16	with FDA requirements, but such compliance does
	17	not establish that warnings in the label were
	18	adequate. FDA regulations permit a drug
	19	manufacturer to change a product label to add or
11:11:46	20	strengthen a warning about its product without
	21	prior FDA approval so long as it later submits
	22	the revised warning to the FDA for review and
	23	approval."
	24	Here's just a picture of the same chart that they
11:12:00	25	used that has the false and misleading data in it. They used

it almost everywhere. Here's a picture (indicating). This is
 the summary basis of approval in 1992, mirror all these
 statements that is being put out there that started with GSK
 talking about no suicide risk, no suicide attempt risk, when,
 in fact, there was a big one.

6 Here is from that, you saw this in my opening 7 statement, and here is a reminder of the 5 deaths that we had documented (indicating). Here is the first time you saw 8 9 silhouettes, sadly you saw a lot more silhouettes during trial. 10 And these are just the people who were taking Paxil that killed 11 themselves in the clinical trials. We don't even have a tally 12 about how many people taking Paxil have killed themselves 13 shortly after getting on to the drug since it's been out in the 14 marketplace because nobody has been able to give you a good 15 number about that, but it's a lot more than the clinical 16 trials, that's what we're dealing with with this drug.

Now, this is to remind you that, from the start, they
had people of many ages, including several in their 50's, and
that 80 percent of these things were violent.

Here was an example of something that Dr. Dunbar put out in '91 pitching this to the big doctor meetings, makes that false statement that subsides and suicide attempts occurred less frequently with paroxetine than placebo (indicating). No, sorry, that's wrong. It was 8.9 times more on paroxetine than placebo.

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	1	Here he is, in 1995, spreading that same stuff with
	2	the same table (indicating). Now, folks who called Dr. Dunbar
	3	as a witness in this case? Let's see. In prosecuting this, we
	4	called the GSK CEO. Who called Dr. Dunbar? He's their head
11:14:03	5	cheerleader on this drug telling the world that it's all safe.
	6	And what did he say? Let's take a look.
	7	(Partial videotape deposition of Geoffrey Dunbar
	8	played in open court).
	9	(Brief pause)
11:20:45	10	MR. RAPOPORT: The champion of the molecule, GSK's
	11	person who spreads the light. One of two things happened here,
	12	either he didn't either he didn't know or he did. Either
	13	way, it's GSK's fault, period.
	14	The champion of the molecule testified in the
11:21:14	15	plaintiff's case that it was even hid from him. And I'll be
	16	interested in listening to the closing of the defendant to see
	17	how at the same time they can argue that Martin Brecher knew
	18	about the run-ins while deny that Dr. Dunbar didn't. Maybe
	19	none of them did, maybe all of them did. Maybe some did and
11:21:42	20	some didn't. It doesn't make any difference because this is,
	21	at a minimum, fault by GSK that resulted in an outrageous
	22	withholding of critically important safety information from the
	23	medical world for years.
	24	I'm going to go through a lot of these papers quickly

11:22:04 25 because time is short and I want to make sure to save some for

damages, but here you have some backup. You can see they did
 various kind of cuts at this. They never had a good odds ratio
 that they can honestly calculate; not really.

Here is one of the more interesting memos about in '99
Daniel Burnham is very troubled about this business of not
telling about the run-ins. And he says that these things are
not comparable, he gives the reasons, and he says:

8 "... the bottom line, we must mention the
9 placebo run-in deaths to reconcile the overall
10 incidents figures; however, we can't combine
11 these placebo run-in deaths with the randomized
12 placebo death rate for the three reasons above,
13 and therefore we're left with more suicides on
14 paroxetine than placebo."

I mean, clearly, in 1999 people at GSK still thought
they were deceiving the FDA, and some of them knew about this.
Dr. Dunbar blamed it on Mike Tydeman. There's an example of a
witness the defendant didn't bring you.

19 All right. So, here's this hypothetical on the board 20 there, here's our proof, this is the document (indicating). Ι 21 raised the hypothetical on December 8th of '99 with the FDA 22 guy: Hey, what about -- you know, what about these run-ins? Ι 23 raised the hypothetical. I inquired about his interpretation 24 of classifying placebo run-in deaths. Specifically, I asked: 25 "... if a person were to die during placebo

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1 2 run-in, i.e. prior to randomization, should that
patient be included?"

3 He clearly stated such a patient should not. Well, 4 you know what, what kind of a trial balloon is that, huh? You 5 have somebody on the phone with the FDA, "hey, let me ask you a hypothetical question?" Oh, oh, I hope they don't figure it 6 7 out because it's a hypothetical because, really, it's real, but a hypothetical, yeah, you know. And then he reports back, 8 yeah, you know, yeah, it didn't go well with a hypothetical. 9 10 And if this company were really honest, they'd fired the people 11 that were involved with this kind of nonsense because you don't call with hypotheticals when they're real. 12

All right. More evidence, more suicide evidence.
Here's the document (indicating), "too many internal
documents," "too many suicides," you know, "lawyers involved,"
what are we going to do. Here's more studies by Mr. Davies
showing, you know, whatever their finding. Here you have some
more falseness in April of 2010 in red.

19This is GSK official again talking to the FDA20April 10th of '02, and in red:

"I assured him this was only an issue in terms of attempts"
this is when they're revealing it:
... only an issue in terms of attempts, the

25 other analysis stood as submitted in the New

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		opening argument - by Rapoport 4307
	1	Drug Application in the 1991 report based on a
	2	New Drug Application."
	3	Now, that's a false statement because it involves
	4	suicides and attempts. You remember, there were the 2 run-in
11:25:26	5	suicides that they slipped into placebo, in addition to the 5
	6	run-in attempts. So, here in 2002, they're not telling the
	7	truth about it. And down in red:
	8	" I indicated similar analysis had been done
	9	for completeness-sake on the more recent 2000
11:25:44	10	database and there's no signal for Paxil there
	11	too"
	12	except there was.
	13	All right. So here is some some of this here
	14	is some internal e-mails going on in '03. There's all kinds of
11:26:02	15	stuff here in fine print. This is the FDA finding out that the
	16	Brits actually were ahead of them on this whole business of
	17	with kids and adolescents, and they are taking a closer look
	18	into this. They have some problems with methodology, but
	19	they're they're, you know, talking about how the sponsor,
11:26:29	20	that's GSK:
	21	" made a feeble attempt to dismiss the
	22	finding about suicides. They're pressing, we
	23	want to move quickly to evaluate the signal."
	24	And evaluate it, they do. The sponsor has not
11:26:43	25	proposed that's the feeble attempt part and let me get

1 this up for you.

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(Brief pause).

MR. RAPOPORT: Here we have, they're questioning
emotional lability, specifically FDA says, what are you putting
on emotional lability. We received this partial response, and
you know, what do we know (indicating).

Let me get all this stuff up here pretty quick. (Brief pause).

9 MR. RAPOPORT: So, you know, their story has been, 10 yeah, well, we couldn't call it suicide or suicide attempt, we 11:27:17 11 had to call it emotional lability because of some dictionary, 12 but the dictionary that they say they're using in their label 13 has suicide attempt in it. And then they make up -- they 14 testify about some other dictionary. And the best they ever 15 did is, Mr. Kraus said, "oh, yeah, you now, that one didn't 11:27:36 16 have it in it," but they never showed you ADEX, they never 17 showed you because they don't have it. There's no reference to 18 ADEX in their label. And we brought the dictionary and showed 19 you that they could've labeled it without lying about it.

And here you see more of that evidence. Here is actually the FDA realizing, I have an old COSTART manual, suicide attempt did exist. The manual has a COSTART, and, you know, so it was in both of them. So, I mean, the FDA is smelling a rat here.

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So, here you have more support. I think I'll save






MR. RAPOPORT: All right. Thank you very much, Your

Honor. And welcome back, ladies and gentlemen of the jury.
So where we broke, we had this odds ratio of 6.7 up.
I think you're familiar with this. After doing the analysis
the way that GSK thought it should be done, they found a
statistically significant 6.7 times increased risk of suicide
association or suicide attempt with our -- for MDD.

8 So, if time was not in issue I was going to show you 9 another movie now that I may show later, but time is an issue, 10 so I'm going to tell you quickly about that movie and save like 11 three minutes.

12 That was Dr. Davies. He was another GSK guy, and he 13 headed up the biostatistician team that worked on this project. 14 And that little video clip, which you also saw on the very 15 first day of evidence when you knew a lot less about all of 16 this than you know now. That was their chief biostatistician 17 certifying that it is, in fact, a 6.7 times odds ratio that 18 came from major depressive disorder.

So, I'm going to time manage, because here's the good news, it's lunch in 20 minutes or maybe 19 minutes. So I'm --I have a lot of ground to cover, so I'm going to cover a lot of these slides fairly quickly and then slow down at the things that we haven't much talked about before and talk about those in more detail.

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So, here you have this moment when they now have this

opening argument - by Rapoport

1 6.7, which is actually consistent with what they knew or should've known all along, because they had 7, 8 times 2 3 increased risk. Here they Document 6.7 times increased risk. 4 And they disseminate this in various pages. I'm flipping 5 through much of the evidence, but they recognized, and this is 6 an interesting one that's up here (indicating), that this 7 information had implications for the label, that they believe 8 that revisions were necessary and in direct communication with 9 healthcare professionals about this 6.7 should be undertaken.

They actually wrote some weak language to do that, which you've seen during the course of the trial, and there it is (indicating). And this 6.7 figure probably understates things, anyway, because they were still, you know, doing things with the data, but I'm not going to spend a lot of time talking about that right now because time is short.

16 So, this next thing that you have here is the 17 Stone/Jones report that you heard a lot about, which came up 18 for our friend, paroxetine/Paxil 2.76 increased risk. And you 19 know by now that any increased risk is bad. And as I showed 20 you at the very start of this case, we started out with risk 21 signal that drove a warning. It's always been there. It comes 22 in different numbers from different sources. Three of them are 23 up there, at 2.76, 6.7, and 5 times, especially violent deaths 24 in the first 30 days, that's the Juurlink article.

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I know you remember a lot of this. And here are a

series of exhibits. I'm going to go through them fast. These are communications that I'm sure you'll hear a fair amount about from the defense, but one of the defenses in this case is, "hey, we told the FDA that we needed to change our label

4 is, "hey, we told the FDA that we needed to change our label
5 and they wouldn't let us," okay. These documents and others
6 show that that is just wrong.

7 I have a meaningful amount of time to speak to you at 8 the end, and after I hear in what way they pitched this idea, then I will respond with evidence and show you why it is the 9 10 case that the FDA never refused to let them put a proper adult 11 warning in the label. They were -- the FDA was focusing on 12 some class-wide labeling when they brought the topic up. Thev 13 didn't return to the topic for years. They haven't returned to 14 it yet. And we'll get into all of that, but I'm not going to 15 spend the time there now other than to point this particular 16 document out and I'll return to that later.

17 So, here you heard from these gentlemen about a 18 warning was required from the start (indicating). I know vou 19 remember Dr. Healy, his qualifications. And the major 20 takeaways from his testimony are up there (indicating). You 21 know that he's one of the world's most prominent experts in 22 drug suicide reaction, in addition to being an interesting 23 gentleman. And he has testified and explained in greater 24 detail, than I ever could, how Paxil can and does cause 25 suicidal behavior in adults of all ages. He explained to you

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opening argument - by Rapoport

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the mechanisms. He showed you the odds ratios that required
 from the start that warnings be given. He showed you pictures,
 like the one I'm flashing. And he gave you lots and lots of
 testimony in great detail at this trial about how it is that
 this drug, this class of drugs, and also this drug in
 particular, causes suicide.

And the reason I'm chugging right through this stuff is just to give you a kind of a preview about there's so much evidence, you couldn't read it all here, and I wouldn't expect you to, but he's given details about every single one of the ways that the drug causes suicide.

12 You know, these are just quick reminders that I'm 13 flashing before on the screen now about the many mechanisms. 14 And here's one that's a little bit easier and I'll pause, 15 because Dr. Healy explained to you that they've known about the 16 suicide risk from the start. He gave you chapter and verse, 17 but he also told you about the 13 ways that GSK hid the suicide 18 signal. And it started with using the washout data, which 19 we've talked plenty about. They never did put up a single 20 witness, did they, that said it was okay to use the washout 21 data? I don't think so.

In my opening comments, I said I don't think you'd hear a witness who said it was okay, and I don't think we have. But there are lots of things that could be said about each of these points. When he was here the other day, he showed you

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I know you remember Dr. Ross. You remember each of

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about -- in a visual about this business of cycle significance
 in P-values and what little difference it makes. I think this
 is a visual image that you'll remember (indicating).

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5 these because they were on the witness stand for a long time.
6 The cross-examination seemed to take forever on these
7 witnesses, although I'm not sure they accomplished much.

8 So, Dr. Ross's major takeaways: GSK was not upfront 9 about Paxil's suicidal behavior risk. And used emotional 10 lability as a coding term which concealed suicide risk. GSK 11 did not warn doctors of the true risk for adults over 24. They 12 could have and should have. And that they had the ultimate 13 responsibility for the label, a point that is borne out by the 14 Court's instructions because that's the law.

15 Here's an expend that was shown during his testimony 16 which showed six points of great importance. And I think 17 you'll remember that he went through and showed you exactly 18 where the label was false and misleading and exactly where they 19 should have put in the association between Paxil and MDD, 20 suicide risk for people of all ages, right up at the top of the 21 headline, so that people like Dr. Sachman and others would not 22 get misled into thinking that it was true that there was no 23 risk for people Mr. Dolin's age, because there was a risk, 24 there always was a risk, and they simply were not candid about 25 it. So, he showed you all the different places in the label

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1 that that could go.

	2	And I hope you remember Dr. Joseph Glenmullen who
	3	testified about and here are his major takeaways about how
	4	we know. And he actually was highly confident that Mr. Dolin's
11:55:05	5	death was caused by this drug. So he, you know, explained that
	6	he had the classic side effects linked to the drug, that the
	7	abrupt change in Mr. Dolin's condition showed the classic side
	8	effects and the classic timeframe were in play. And that's
	9	what my next big board is all about. So, I'm going to walk you
11:55:28	10	through another big board here (indicating).
	11	So, and you might want to ask the defense lawyer
	12	well, you can't ask but maybe he'll address why it is that he
	13	said that Wendy Dolin's testimony was the only testimony in the
	14	case about any changes that Mr. Dolin had during this last
11:55:50	15	six days of his life.
	16	Well, this board is developed from an exhibit that was
	17	entered into evidence during Dr. Glenmullen's testimony, and
	18	this shows all of the evidence of changes.
	19	And so which part is Wendy Dolin's? Right here
11:56:10	20	(indicating), okay. Other than that, she doesn't appear again.
	21	So this is testimony coming from Dr. Salstrom and her records;
	22	coming from Dr. Salstrom and her records; coming from Sydney
	23	Reed and her records; coming from Mike LoVallo, who testified
	24	before you; coming from Sydney Reed; coming from Bari Dolin,
11:56:30	25	and coming from Mr. Pecoraro (indicating).

And so here, I'm going to do this guick: Here's the 1 2 timeline. We know that yellow is where the drug is going to 3 start. Okay, here's the timeline: 4 First visit with Dr. Salstrom, June 29th. Mr. Dolin 5 told her he had no history of suicidal ideation or attempts. 11:56:46 6 The next entry is July 6th, the second visit with Dr. 7 Salstrom. Client was receptive, expressed modification to 8 learn and use new strategies. He starts the paroxetine. 9 Now, Wendy Dolin did notice on Sunday, "increased 10 agitation, pacing, distorting thinking, loss of sleep, and loss 11:57:11 11 of appetite." 12 Dr. Salstrom, in her records, noted fear of his passive suicidal thoughts, and the suicidal thoughts entered 13 14 the situation after he was on Paxil for two days, okay. I'm 15 going to listen carefully to this nonsense story that Dr. 11:57:27 16 Rothschild tells where he tries to make it as if suicidal 17 thoughts entered here, but that isn't what the records say and 18 it isn't what Dr. Salstrom said. Dr. Salstrom documents some suicidal thoughts they 19 20 were because of the Paxil. It's one of the changes. 11:57:43 21 Wendy Dolin that night said, "I had never seen that 22 kind of anxiety or agitation in him. It was heightened, everything was increased." 23 24 But you can forget Wendy Dolin, look at Sydney Reed in 25 that last -- in that last session: 11:57:57

opening argument - by Rapoport

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"Mr. Dolin called to schedule a same-day session. He had never done that before. Said he was having maybe a nervous breakdown."

4 And the last session, it was the most anxious she had 5 every seen him. "Had a wish to not wake up but without a 6 plan." There was Friday, there was supposed to be a meeting 7 with a client. He felt disconnected from his wife. He seemed -- it seemed important to know that he felt disconnected, 8 9 because in reality, they were very connected. He didn't sit 10 still. Was more agitated. He didn't calm down in the same way 11 he calmed down before. Shifted around his chair nervously.

12 Same day, we have all of these observations from Susan 13 Miniat: Not present, preoccupied, completely unlike his 14 routine behavior, noticeably off, unusual for his behavior. He 15 apologizes. His demeanor on the phone: Vague, distance, 16 disparing, sounded off. Unusual behavior, not like him, 17 uncharacteristic. And she answers, yes, that there had been 18 six conversations that day -- between July 1st and July 15th, 19 and that that day was the first time that he sounded that way.

And then we get to the day of where Mike LoVallo testified he was uneasy, it was really a sort of much-ado-about-nothing kind of situation, but he was having trouble sorting it out. Thursday morning in particular, fairly simple, straightforward situation, but he was having trouble sorting it out. His concentration wasn't right. Just the way

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he was intellectually to process things wasn't normal. He had
 a conversation the first time, then had it again, going over
 the same thing; very uncharacteristic.

And for the first time in their very long

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5 relationship, Sydney Reed calls Mr. Dolin at 10:30. She'd 6 never done this before. She was just uneasy about what was 7 going on with him. Asked him to think about getting on a 8 different medication, maybe antianxiety. She'd never done this in the 36 years that she had been in practice. 9 He was 10 different than she had ever seen him before, the night before. 11 And she said he seemed a little weird, it was weird because he 12 was always excited to make plans to work out, but here he was 13 cold and distant.

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And Mr. Pecoraro, of course, told us about the pacing like a polar bear before we all know what happened.

16 This is the evidence that fits perfectly with what we17 know the syndrome is that causes suicide from this drug.

18 So, I'm going to -- these are Dr. Glenmullen's 19 opinions I put before you. And we have various exhibits 20 showing what the actual care was in order to control the gross 21 overstatements of the defense about what was happening with Mr. Dolin's care, because the truth is, he never lost a day from 22 23 work, he never had a psychiatric hospitalization, he never knew 24 of any heavy psychiatric diagnosis, he was getting some talk 25 therapy predominantly and getting help from meds that he and

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1 everybody else thought were not very scary. 2 Here, Dr. Glenmullen testified about these various 3 things that I'm flashing before you. He went through a 4 differential analysis. He showed you the drug paroxetine was 5 in the decedent's system and there were no other drugs. He 12:01:19 showed you the perfect fit between the syndrome and what we 6 7 have. Now, lots of stuff here that I'm just going to zip 8 through and not show. We'll see how fast I can get them to go, 9 about all these defense experts. If time allowed, I would be 10 12:01:36 11 talking to you about every one of them and the problems with 12 them, and time will allow because I'll come back and talk about 13 these things. 14 But here's the bottom line, this is a clear liability 15 case: 12:01:50 16 "... your most important duty in this case will 17 be to determine the amount of money that will 18 fairly and reasonably compensate the Dolin family for the wrongful death damages and the 19 20 Estate of Stewart Dolin for the survival 12:02:00 21 damages." 22 Now, here we have again, and we've briefly talked 23 about this, this is what the money damages are all about. We 24 have two major factors that go into this: What is the severity 25 of the harm and what is the duration of the harm, because some 12:02:17

opening argument - by Rapoport

1 harms are so horrid that even if they are very short in 2 duration, they're worth a million dollars or more. Some harms 3 are less horrid and have a different scale that would apply to 4 that. But how bad is it, is one question, and for how much 5 time is it suffered, those are really the big factors. 12:02:38 6 And it's important to note the things that are 7 improper factors. So, the Court will be telling you that you have to follow the law, and you have to follow the evidence. 8 So, there are a lot of examples of the kinds of arguments that, 9 10 if you hear them back there, you should explain to people, 12:02:54 11 that's an outside factor, not to be considered. And here's a 12 list of them: 13 The money won't do any good. The plaintiff doesn't 14 need that much money. 15 A large verdict will drive up prices. 12:03:04 16 I'm afraid of what my neighbors will think. 17 I've seen worse. 18 No matter what the evidence was, I won't award more 19 than a certain amount. The claim was not proved beyond a reasonable doubt. 20 12:03:14 21 Every one of these is an example of an improper factor 22 that would be improper to consider. And if anybody makes these 23 arguments, I urge you, please, to point out those are improper factors, not allowed. 24 25 So now we get to it. Your call to action. Stewart 12:03:30

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Dolin's survival damages. He suffered for six days, and that
 board summarizes some of that suffering.

And that suffering led to, in one way or another, an involuntary jump in front of a train, we believe, and so based on an irresistible impulse. And six days of emotional distress and pain and suffering, what would be an appropriate award for that? There's the evidence that it's based on.

8 And we do have a right to make suggestions to you 9 about damages. What we believe, based on the evidence and 10 based on the law, that a proper allocation for that item of 11 damages is \$3 million. And that's what I put on there.

Now, you should understand that awards of damages are left to your -- you are the conscious of the community. And so we are allowed to give you information like I just did, but you are free, as jurors, to weigh the evidence and award less or more. We're just showing you what we believe the evidence shows.

So, then we get to the wrongful death damages. What amount of money will equalize the harm for the wrongful death. And you should know, and you'll get an instruction on this, that when you are dying you leave a widow and you leave children. The law recognizes a presumption that they have each sustained some substantial pecuniary loss.

24 You've seen in evidence, and I show you again, the 25 earnings history of Mr. Dolin, and that covered the full year

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of 2009, and you also have seen in evidence the earning
 information for the partial year of 2010.

3 And here is a summary that we've prepared that lays 4 out the calculations of just the money loss. So, you can see 5 that his earnings for 5-year average of full years were \$1.2 million and change. I put it on there as 1,200,285. Here 6 7 you can see his date of birth, as well as the date of his 70th 8 birthday, which is the time when he would have to surrender his 9 equity partnership, though his law firm was free to continue 10 paying him in another capacity of counsel, typically.

11 So, in any event, we have a period of past loss here 12 running from the day after the death through today or tomorrow, 13 which is 6.745 years, and you can see that. We have a period 14 of future loss running the day after tomorrow through his 70th 15 birthday, that's our contention. If you think that he would work longer than 70, and there are people that do, including 16 17 some in this room, then you are free to make any determination 18 about how long you would think he may work, shorter or longer. 19 This is to your discretion.

But we've done calculations for you. So, the past amount of earnings lost is the first figure. I put down there a little more than \$8 million, 8,095,922.32. The future loss has to be reduced to present value. And we have in evidence, but it hasn't been mentioned to you yet, that the 5 year T-bill rate is currently 1.97 percent, that is an appropriate rate to

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use for present-value calculations. And we have done that
 based on the assumption that the loss of money goes to age 70.
 And that's the second figure that you see there, \$6.7 million
 and change.

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5 So, the sum total claim for money lost is 6 \$14,826,047.97. It's almost \$15 million. Some people say 7 that's a lot of money, but the reality is he was a substantial 8 wage earner and he was cut down or cut himself down, whatever 9 it is that you determine, but what happened to him happened at 10 the peak of an earning capacity, and it happened to be a very 11 large earning capacity which is why we get numbers like this.

So, while the money losses are substantial in this case, I submit to you that the non-money losses are even greater. And I know that you don't have to be reminded about what sort of a family man he was. I think you've had an opportunity to see glimpses of Stu Dolin's life. Glimpses of who he was at home, at work, and at play.

And this guy was not a guy who had any reason to take his life. He was not a guy whose pattern of life suggested that his life should be over at 57. And you don't need to go much further than these few pictures or to remember the 11-minute video, or to think about the honor that his law firm has given him in spite of the circumstances of his death.

There are a lot of people that believe that Stu Dolin died because paroxetine induced his death, and we hope that you

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1 so find.

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2 So, what is the bottom line, folks? In wrongful death 3 damages, where you have the power to compensate, what we have 4 here are the damages components, the economic loss that I just 5 showed you, close to \$15 million, and then the noneconomic 6 losses for three people who sit before you. Stu Dolin's life 7 expectancy was 24 years, so collectively between the three of 8 them they have 72 years of loss, 24 years each. Not to mention 9 the fact that when you lose a parent under these circumstances, 10 the loss may not end when his normal life expectancy would have 11 been up. 12 So, for the economic loss of almost 15 million

dollars, and for those 72 collective years of non-money losses,
I submit to you that a total verdict of \$36 million would be
appropriate when added to the survival damages for what Mr.
Dolin suffered himself of \$3 million, that is a request for
\$39 million. We believe it's fully supported by the evidence
and by the law in this case.

I'm grateful that we have a family that had the means
to bring this lawsuit to you, because it's about time that one
of these lawsuits was heard and decided by this jury.

MR. BAYMAN: Objection, Your Honor. Now, this is -THE COURT: Sustained.
MR. BAYMAN: Thank you.

25 Ask that that be stricken, Your Honor.



	opening argument - by Rapoport	4328
1	(Luncheon recess taken from 12:15 o'clock p.m.	
2	to 1:15 o'clock p.m.)	
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	opening argument - by Rapoport 4329
1 2	IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION
3	WENDY B. DOLIN Individually and as)
4	Independent Executor of the Estate of STEWART DOLIN, deceased,
5	Plaintiff,
6	vs. Chicago, Illinois
7	SMITHKLINE BEECHAM CORPORATION
8	D/B/A GLAXOSMITHKLINE, a Pennsylvania
9	Defendant.) 9:220 o'clock a.m.
10	
11	VOLUME 20 A <u>TRANSCRIPT OF PROCEEDINGS</u> BEFORE THE HONORABLE WILLIAM T. HART
12	BEFUKE THE HUNUKABLE WILLIAM I. HAKT
13	For the Plaintiff:
14	BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
15	BY: R. Brent Wisner Michael L. Baum 12100 Wilsbirg Boulevard
16	12100 Wilshire Boulevard Suite 950 Leo Appeleo - Colifornio 00025
17	Los Angeles, California 90025 (310) 207-3233
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22	Court reporter:
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24	219 South Dearborn Street Room 2504 Chicago Illipois 60604
25	Chicago, Illinois 60604 (312) 435-5895

	opening argument - by Rapoport 4330
1	Appearances (continued:)
2	
3	For Defendant GlaxoSmithKline:
4	KING & SPALDING
5	BY: Todd P. Davis Andrew T Bayman
6	Heather Howard 1180 Peachtree St Ne
7	Atlanta, Georgia 30309 (404) 572-4600
8	KING & SPALDING LLP
9	BY: Ursula M. Henninger Suite 3900
10	100 N Tryon Street Charlotte, NC 28202
11	(704) 503-2631
12	SNR DENTON US, LLP
13	BY: Alan Scott Gilbert 233 South Wacker Drive
14	Suite 7800 Chicago, Illinois 60606
15	(312) 876-8000
16	
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25	(The following proceedings were had out of the





		opening argument - by Rapoport 4333
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01:20:18	5	
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01:20:26	10	(The following proceedings were had in the
	11	presence of the jury in open court:)
	12	THE COURT: All right. Thank you very much, ladies
	13	and gentlemen.
	14	Please be seated, ladies and gentlemen. We will
01:20:42	15	resume.
	16	A word more about the schedule. I've concluded that
	17	this afternoon will not leave us enough time to instruct and
	18	allow you to begin deliberations. So, what I'm going to do is
	19	hear all the arguments today, send you home, even maybe a
01:21:02	20	couple of minutes early, if that's possible, and then we'll
	21	instruct you at 9:30 in the morning, and then you'll have the
	22	case. And I assure you, the instructions won't take long, so
	23	you'll have the case tomorrow.
	24	All right. Thank you.
01:21:14	25	Mr. Bayman.

		closing argument - by Bayman 4334
	1	CLOSING ARGUMENT ON BEHALF OF DEFENDANT
	2	MR. BAYMAN: Thank you, Your Honor.
	3	May it please the Court, counsel, ladies and
	4	gentlemen.
01:21:20	5	First of all, I want to thank you for being here every
	6	day, for working hard, and for listening attentively. I thank
	7	you on behalf of myself and on behalf of my team behind you. $$ I
	8	also thank you on behalf of GSK. Mr. Andrew Boczkowski from
	9	GSK has been here every day also and he also thanks you for
01:21:30	10	your service.
	11	You've had to work hard to absorb probable more than
	12	you'd ever expected when you first sat down in that jury box
	13	nearly 5 weeks ago. We're lawyers and this is our job, but
	14	you've taken time away from your families, your work, and your
01:21:55	15	friends to do the hard work of jurors, and we really appreciate
	16	it. This is very important service.
	17	We, on the defense side, have done our case to bring
	18	you the case as quickly as possible. And we didn't call as
	19	many witnesses as the plaintiff did, and there are some reasons
01:22:08	20	for that.
	21	Judge Hart is going to instruct you that he informed
	22	us prior to the trial that a witness would only be permitted to
	23	be called once, and that each side should use that opportunity
	24	to question the witness. So, for that reason, he's going to
01:22:23	25	instruct you, you should not consider whether a particular

witness was called in the plaintiff's case or in the
 defendant's case. There were witnesses we would've called in
 our case that were called in the plaintiff's case, and we
 examined them in the plaintiff's case in order to move the
 trial along.

6 Now you get to do the hard work. You've listened to 7 many witnesses offer detail testimony on scientific concepts, such as psychiatry, statistics, law-firm economics, and many 8 other issues. This is hard stuff, complex stuff, even for 9 10 people who do it every day, but both sides selected you as 11 jurors because we believe you would work hard to listen to all 12 the evidence and decide the case based on only what you heard and saw in this courtroom. 13

You're not in that jury box by default. Both sides believe that you were fair and objective, that you could give both GSK and Mrs. Dolin an equal shake even though one is an individual and the other is a corporation. You promised us you would do that when you swore your oath as jurors at the start of the case, and we are confident that you will deliver on that promise.

As I talk about the evidence this afternoon, please remember, as Judge Hart will instruct you tomorrow, the plaintiff has the burden of proof. When you get the jury instructions in this case, you will see that in a case such as this, a civil case, the burden is on the plaintiff to prove

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each and every essential element of her claim by a
 preponderance of the evidence. And to prove by a preponderance
 of the evidence means that the plaintiff must persuade you that
 considering all the evidence, something is more likely true
 than not true.

6 As you've heard, the claim in this case is that 7 paroxetine causes suicides in adults over age 24, and that 8 because of that, the paroxetine label was somehow inadequate 9 for not stating this risk. That Dr. Sachman was not aware of 10 it, and for that reason he prescribed paroxetine to Mr. Dolin 11 which caused Mr. Dolin to take his own life. Plaintiff, not 12 GSK, has the burden of proving each of the following:

First, that paroxetine causes suicides in adults over age 24. Mr. Dolin was 57 years old at the time of his death, and for the plaintiff to prevail she must prove that the scientific evidence establishes that paroxetine causes people of Mr. Dolin's age to commit suicide. If you do not believe that the plaintiff has proven this, then your verdict must be against the plaintiff.

Second, the plaintiff must prove that the paroxetine labeling was not adequate. That the paroxetine labeling could have and should have contained the warning that paroxetine causes suicide in adults over age 24. If you find that the paroxetine label accurately stated the risks associated with paroxetine, then your verdict must once again be against the

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1 | plaintiff.

Third, the plaintiff must prove that Dr. Sachman was not aware of the risks of paroxetine in adult patients when he made the decision to prescribe paroxetine to Mr. Dolin. If you believe that Dr. Sachman knew about the risks of paroxetine before he last prescribed paroxetine to Mr. Dolin, then your verdict must be against the plaintiff.

Finally, the plaintiff must prove that Mr. Dolin's
suicide was caused by his use of paroxetine and not, as the
evidence has shown, by his longstanding problems with anxiety
and depression and all the various struggles and work stresses
he faced in the months and days alluding up to his death.

If you find that Mr. Dolin's death was caused by his
longstanding problems with anxiety and depression when combined
with the work stresses, then your verdict must be against the
plaintiff.

Based on the evidence the plaintiff has brought you,
the plaintiff has failed to prove any of these points, and as a
result your verdict should be against the plaintiff.

Had GSK not decided to call a single witness, had GSK not decided to offer any evidence, plaintiff would still have the burden of proving all these things on the screen, she has to prove them all. And she has to prove each of these things by a preponderance of the evidence. That means when you weigh the evidence on each of these points, looking at those scales

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1 that Mr. Rapaport showed you, the scales must tip to the 2 plaintiff's side. If you think the scales are balanced, if you 3 think it's 50/50, then the plaintiff has not met her burden of 4 proof on that issue and you must find against the plaintiff. 5 I told you in your opening statement something very 01:26:59 6 important, I said don't check your common sense at the door, 7 use your common sense. In fact, you're going to be instructed 8 by Judge Hart tomorrow to use your common sense in weighing the 9 evidence in this case. 10 Some of the issues you've heard are complex and 01:27:17 11 scientific, but your common sense will guide you to the 12 Don't be fooled by conspiracy theories or speculation answers. 13 from the plaintiff. The plaintiff has spent a lot of time in 14 this case, perhaps most of the case, telling you about things 15 from the late 1980's and the 1990's that don't have anything to 01:27:34

do with the four issues that they must prove.

17 It's like that white noise that comes on the speakers 18 every time we go to sidebar, it's there to distract you, to 19 keep you from hearing what is really going on. Plaintiff has 20 done the same thing throughout this case, tried to distract you 21 with white-noise issues to draw your focus away from what 22 really matters.

This case, as I said in opening, is about Stewart Dolin, and what happened to Stewart Dolin after he was prescribed paroxetine in 2005 and then later in 2010, that's

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1 what matters in this case.

I'm going to try to point out some of those
white-noise issues the plaintiff has thrown up to you during
the course of my closing argument, but if you rely on your
common sense and the evidence you've heard, you'll reach the
right conclusions in this case.

Now, I told you in my opening statement that there
would be four important factual questions you would have to
answer. So, now that you've heard all the evidence on both
sides, let's look at what the evidence tells us about the
answers to each of these four questions:

First, why did Mr. Dolin take his own life.

13 Second, what is the scientific evidence regarding14 Paxil and suicide.

15 Third, did GSK communicate with the FDA and doctors16 about the possible risks of Paxil.

And fourth, was Mr. Dolin's doctor aware of thepossible risks of Paxil or paroxetine.

19 I'm going to talk to you a little bit about the second20 and the third questions, and then my law partner, Ms.

Henninger, is going to come up here and talk about the firstand last questions and conclude our argument.

Question one, does paroxetine cause suicide in adults
over age 24. This is a question of science, and you must
consider the scientific evidence, but in answering these

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questions, ladies and gentlemen, you don't have to start from
 scratch. You have experts to guide you.

The FDA has spoken, and it has spoken loudly. You heard how the FDA, a neutral group of science who are not a party to this lawsuit, they don't have a dog in this fight, has looked at this question many times. FDA has said that when analyzing the issue of whether SSRIs, like Paxil or paroxetine, increase the risk of suicide, you must look only at the placebo-controlled portions of placebo-controlled trials.

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10 The FDA has spoken through its words, and through its 11 silence, through it's action and its inaction, through what it 12 has done and what it has not done. Let's look at the words FDA 13 used. FDA wrote, "when it completed its adult suicidality 14 analysis, 2007:

01:30:2015"In contrast with the previous FDA review of16pediatric studies, the pooled estimates of17studies of the adult population support the18no-hypothesis of no treatment effect on19suicidality."

01:30:3620You heard from Dr. Robert Gibbons from the University21of Chicago about what those words mean:

22 "... when FDA looked at all the data in 2006, it
 23 found no increased risk of suicidality among
 24 antidepressants when used with adult patients."
 01:30:53 25 Dr. Gibbons also discussed how when FDA assessed

1 paroxetine or Paxil specifically, it found no increased risk for Paxil and suicidal thoughts or behavior, which was the 2 3 primary analysis the FDA focused on. 4 The FDA said something very similar here: 5 "The net effect appears to be neutral on 01:31:08 suicidal behavior, but possibly protective for 6 7 suicidality for adults between the ages of 25 and 64, and to reduce the risk of both 8 9 suicidality and suicidal behavior in subjects 10 aged 65 years and older." 01:31:25 11 Here is what the FDA also said, not in a memo or in a 12 report, but in the very language it required GSK and other 13 antidepressant manufacturers to put in the label, in the black 14 box right at the front, it said: 15 "... the studies analyzed did not show an 01:31:44 increased risk in suicidality with 16 17 antidepressants compared to placebo in adults 18 beyond age 24. There was a reduction in risk 19 with antidepressants compared to placebo in 20 adults age 65" 01:31:58 21 But the label also says: 22 "... patients of all ages who are started on 23 antidepressant therapy should be monitored 24 appropriately and observed closely for clinical 25 worsening, suicidality, or unusual changes in 01:32:14

behavior."

You've heard some of the plaintiff's experts come in here and say, "oh, that's just disease management." Use your common sense, ladies and gentlemen, ask yourself if that is a warning of a risk associated with the use of antidepressant therapy like paroxetine or Paxil.

FDA has determined that in adults age 25 to 64, there
is not an increased risk in adult ages and that the medications
protects against suicidal thoughts or behavior.

10 So as you can see in this slide, if you're in the 24 to 64 age range, the FDA says SSRIs are possibly protective, 11 12 meaning not only do they not cause suicide, but they might 13 protect against it, and then if you're over 64 the evidence is 14 that SSRIs reduce the risk of suicide, they are protective. 15 Use your common sense again here, ladies and gentlemen. Where 16 does Mr. Dolin, who was age 57 at the time of his death, fit 17 into this age range? He is not in a category of increased 18 risk.

But more importantly, ladies and gentlemen, let's look at what the FDA never said. The FDA has never said Paxil causes suicide, never says paroxetine causes suicide, never said SSRIs cause suicide in adults. The FDA has never said the very thing that the plaintiff says the label should say.

Let's look at the FDA's actions. You heard from Dr.Ross that every time GSK asks the FDA to approve paroxetine for

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		closing argument - by Bayman 4343
	1	a new indication, like anxiety or excessive compulsive
	2	disorder, or GAD, FDA had to make a determination that the
	3	medicine was both safe and effective.
	4	You've seen this slide before. In all the various
01:34:03	5	times that the FDA made this determination, again and again and
	6	again, that Paxil was safe and effective.
	7	And when it did that each time, FDA expressly stated
	8	that it was approving the labeling for Paxil because
	9	ultimately, ladies and gentlemen, the FDA must approve Paxil's
01:34:23	10	label before Paxil can be sold in the United States.
	11	Now, the timing of the FDA's approvals of the Paxil
	12	label is important. Many of these approvals of the Paxil label
	13	by the FDA followed GSK's significant submissions regarding
	14	deaths or suicides.
01:34:40	15	First, the FDA approved Paxil for use in major
	16	depression in 1992, which was just after GSK submitted the 1991
	17	suicidal report that the plaintiff has talked so much about.
	18	Second, the FDA approved Paxil for GAD, generalized
	19	anxiety disorder, the condition Mr. Dolin had, a year after GSK
01:35:02	20	submitted the report about deaths in clinical trials in 1999.
	21	Third, FDA approved Paxil for the treatment of PMDD, a
	22	few months after GSK submitted the apples to apples reanalysis
	23	of suicide attempts from the New Drug Application data looking
	24	only at the controlled portions of the placebo-controlled
01:35:25	25	trials.

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	1	What's plaintiff's response to these approvals? Well,
	2	Dr. Healy says the FDA was violating its own regulations. In
	3	fact, Dr. Healy said FDA had all the data it needed since 1990.
	4	He said it a long time ago, during his very first trip to that
01:35:44	5	witness stand (indicating).
	6	So let's remind ourselves. I asked Dr. Healy first,
	7	"is it your claim"
	8	"Isn't it your claim that the FDA had all the
	9	data it needed to add a suicide warning in 1989
01:35:56	10	and that FDA breached its own regulations and
	11	opted not to require warning?"
	12	His answer was:
	13	"Well, I didn't say 1989. I said it was around
	14	1990. I can find the data when Dr. Lieber made
01:36:14	15	this offer, if you wish. In terms of breaching
	16	regulations, the person who seemed to breach the
	17	regulation in this case may be Dr. Brecher."
	18	So I had to impeach him with his own deposition, and
	19	then he admitted that he previously had said this:
01:36:25	20	"I'm claiming the FDA had data from 1989 onwards
	21	that showed a consistent increase in the risk of
	22	these drugs, and for whatever reasons, in breach
	23	of their own regulations, which state if there's
	24	a reasonable risk the drug may be linked to a
01:36:41	25	series problem there ought to be warnings, and
		closing argument - by Bayman 4345
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	1	the FDA opted not to require the companies to
	2	warn."
	3	Dr. Healy concedes that the FBI, in his opinion, had
	4	all the data it needed to issue a warning from 1989 onwards.
01:36:56	5	So let's stop there. If FDA had all the data it
	6	needed in 1989, the year that GSK submitted the New Drug
	7	Application, then obviously GSK didn't hide any risk. Dr.
	8	Healy can't have it both ways.
	9	Next, Dr. Healy said FDA breached its own regulations.
01:37:17	10	He didn't say GSK breached any regulations, he said the FDA
	11	did. And, in fact, there's no evidence in this case that GSK
	12	breached any regulations related to the issue of data regarding
	13	suicide risk and paroxetine, none. Any suggestion otherwise,
	14	any references to breach of regulations is just more white
01:37:36	15	noise.
	16	Finally, Dr. Healy says for whatever reason, FDA opted
	17	not to require the companies to warn. Dr. Healy lays the
	18	decision at the feet of the FDA. He says FDA had the data he
	19	thinks supported a warning from 1989 onwards and it opted not
01:37:54	20	to require the companies to warn.
	21	And, ladies and gentlemen, that gets us to the
	22	fundamental problem with the plaintiff's claim in this case.
	23	The plaintiff just disagrees with the conclusions the FDA has
	24	reached about whether there is a risk or not.
01:38:08	25	Her experts' claim is really not about what GSK did

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submit or didn't submit. It's about the conclusions that the
 FDA has consistently made based on the data from 1989 to 2017.
 The plaintiff just thinks the FDA got it wrong.

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4 But, ladies and gentlemen, the FDA didn't get it 5 It reached the same conclusion that GSK scientists had wrong. 6 reached, that Dr. Kraus has reached, that world-renowned 7 experts like Dr. Gibbons and Dr. Rothschild have reached. When you look at the totality of all of the controlled studies, 8 there's no increased risk of completed suicide or suicidal 9 10 thoughts or behavior in adult patients taking Paxil or 11 paroxetine.

FDA spoke through its actions, over and over, in
approving Paxil, but it's also spoken through in its inaction,
through the things it has not done. FDA has never requested
that the label say Paxil causes suicide in adults over age 24.

This has been a long trial, and I'm sure everyone is ready for it to be over, but if we were here a couple weeks longer we'd come to an unusual milestone: May 2, 2017, will mark a decade since the FDA's announcements of findings from its 2006 analysis. For the past 10 years, FDA has taken no action regarding the Paxil or paroxetine label in suicide, suicidal thoughts or suicidal behavior.

Why is that? Because as you heard from Dr. Kraus and Dr. Gibbons, there is no larger analysis of placebo-controlled studies than what FDA analyzed in 2006. In fact, that

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And this is where you get to use your common sense

testimony was unrefuted by the plaintiff and even by Dr.
 Healy's return to the stand last Thursday. That fact, and the
 plaintiff's very silent admission on it is very important.

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5 again, ladies and gentlemen, when it comes to the FDA's 6 actions. What do you believe is more likely, that the FDA, who 7 had independent scientists analyze the data correctly, interpreted that data in 2006 and 2007 when it concluded there 8 was no increased risk in adults above the age 24, and that the 9 10 labeling has been accurate for 10 years? Or that the FDA got 11 it wrong and has gotten it wrong for 10 years and the 12 plaintiff's professional experts are correct?

Is it believable that Paxil or paroxetine and all SSRIs cause suicide? That there would have not been -- there would've been complete silence on this issue for 10 years from everyone except paid experts? Do you think if these medicines were causing suicide, someone will have spoken up other than the plaintiff's experts?

19 If the plaintiffs are right, where are the studies 20 that say paroxetine causes suicide? Where are the statements 21 from the American Psychiatric Association, the American College 22 of Neuropsychopharmacology who Dr. Healy called as experts on 23 the effect of medications? Where are there calls for more 24 warnings? There are none, ladies and gentlemen.

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And it's not as if this issue hasn't been studied.

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Doctors, scientists, the FDA have been looking at this issue
 since before Paxil was first approved.

You heard about that Teicher/Cole article that raised an initial question about Prozac back in 1991. So for 25 years or more the question of SSRIs and suicide has been under discussion. And during those 25 years, FDA has never said that SSRIs or paroxetine cause suicide in adults or that there's an increased risk in patients over age 24. In fact, FDA has said the opposite.

10 So, that is what the FDA has said and not said, done 11 and not done, to help you answer the question of whether 12 paroxetine causes suicide in adults over age 24, but there's 13 been even more evidence in this case, ladies and gentlemen.

First of all, we brought you Dr. Kraus. Dr. Kraus, Dr. Kraus left the practice of medicine and teaching medical students to join GSK so that he could help develop medicines that would help people. He is the scientist who knows this medication better than anyone. He sat in that witness chair and he gave you straight answers, not just to my questions but also Mr. Wisner's question.

You will be instructed by Judge Hart tomorrow that when you evaluate the testimony of witnesses, you may consider the ability and opportunity the witness had to see, hear, or know the things the witness testified about. Dr. Kraus was there in 2006 and was part of GSK's analysis of the adult

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suicide data. He personally drafted the new labeling that GSK
issued in 2006. He personally participated in conferences with
the FDA about labeling. He saw the labeling corresponded as it
was happening in real time. He's the only witness that you've
heard from who has first-hand knowledge. And what did he tell
you? He said that based on everything he knows, paroxetine
does not cause suicide in adult patients.

8 On that key point, the plaintiff never challenged Dr. 9 Kraus. Mr. Wisner did not try to prove Dr. Kraus wrong in the 10 most fundamental scientific question in this case. Instead. 11 Mr. Wisner focused his guestion on things that happened 12 25 years ago, like run-ins and coding issues. He did not 13 confront Dr. Kraus with any new studies or any new data. And 14 he never questioned Dr. Kraus about any studies that came out 15 after FDA's 2006 adult suicidality analysis.

Again, why did the plaintiff fail to do this? Because there were no studies that provided newly acquired information after FDA's comprehensive 2006 adult suicidality analysis. And with no newly acquired information, GSK had no information to submit to FDA to change the Paxil label. And that is for good reason, there is no published study that shows Paxil causes suicide in adults; none; zero.

Now, let's talk about GSK's 2006 analysis for a few
minutes. Dr. Kraus, who again was personally involved in that
analysis, explained the results to you in great detail. First

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closing argument - by Bayman

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1 and foremost, there was no increased risk in any primary 2 endpoint. You've heard throughout the course of this trial 3 that the primary endpoint is the main question that is being 4 investigated in this study. It is the most important question. 5 Plaintiff doesn't like the primary endpoint that GSK 01:44:58 6 Dr. Healy said it was arbitrary and he doesn't know why chose. 7 it was chosen. But that's not true. Dr. Kraus explained that 8 the FDA chose to use suicidal ideation and behavior as the 9 primary endpoint because that was how the signal in pediatric 10 patients was picked up. 01:45:18 11 You also heard Dr. Gibbons, who is not with GSK, say 12 that was the right choice, because it had a greater likelihood 13 of detecting a real drug effect if there is one. 14 Now, why don't the plaintiff's experts like the 15 primary endpoint? Because they don't like the results. 01:45:35 16 There was also no increased risk on the primary 17 endpoint in any subgroup in GSK's analysis. 18 Dr. Kraus also told you the results when GSK looked 19 specifically at patients Mr. Dolin's age. He showed you this 20 chart and this data analysis. It shows no difference in the 01:45:55 21 rates of between paroxetine and placebo in the 25 to 64 age 22 group. 23 And Dr. Kraus showed you the article GSK published, 24 the Carpenter paper, in which Dr. Kraus is a co-author, in a 25 peer-reviewed publication, and those results stated that GSK 01:46:17

did not see an increase in suicide in adults over 25.

Now, of course, there was one finding in the MDD
subgroup that Dr. Kraus told you about, and I want to talk
about that for a minute.

5 GSK did over 90 analyses in its 2006 analysis and only 6 one showed an increased risk. It was the secondary endpoint in 7 the MDD group. And you heard the testimony that it was driven 8 completely by 11 suicide attempts out of 3,455 patients with 9 MDD. That means, ladies and gentlemen, that 99.6 percent of 10 the patients in those trials did not have suicide attempts. 11 You'll also remember, there were no suicides in these trials.

But GSK didn't hide it. It didn't try to sweep that
finding under the rug. It did what a reasonably careful
corporation should do, it immediately added that information to
its label subject to FDA approving the change.

16 It took responsibility for changing the label without 17 prompting by the FDA. And then it investigated the finding 18 further. Dr. Kraus himself did it personally, because when --19 that's what you do when you find something you're not expecting 20 in a secondary endpoint. You ask, is this real, what does it 21 mean. That is what a reasonably careful corporation should do, 22 ladies and gentlemen, and that's what GSK did.

From a statistical perspective, Dr. Gibbons explained why increased finding in MDD, in the GSK analysis, was not real. He explained that the placebo rate in the MDD placebo

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group was abnormally low. And as you can see from this slide,
 the placebo rate in the FDA dataset a much larger dataset was
 four times higher.

Dr. Gibbons also showed you how that one result was
inconsistent with a lot of other findings in GSK's analysis,
that it would make no sense for paroxetine to reduce suicidal
thoughts but to increase suicidal behavior.

8 The 6.7 odds ratio that the plaintiff focuses on was 9 not due to a high number of suicidal attempts on paroxetine, it 10 was due to an unusually low number of placebo suicide attempts.

But Dr. Kraus went beyond that. He did a deep dive into the 11 patients that made up that MDD subgroup finding. He studied those patients from the perspective of someone who has treated thousands of patients with depression and anxiety, and he explained to you what he found.

You remember this slide showing the characteristics of
the 11 patients? Let's not forget, non of these were suicides,
there were no suicides in the population, only attempts.

He told you that he went through all the case report forms himself. The case report forms are the raw data that discuss how the patient did in the trial and how a patient responded after starting paroxetine or placebo. He did an analysis of those patients and he published it in a peer-reviewed journal.

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Now, the plaintiff must not have liked what Dr. Kraus

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said because they flew Dr. Healy all the way back here from
 Wales. They had him sit in a hotel room for four days just to
 come and tell you that he disagrees. He was already back here,
 ladies and gentlemen, before Dr. Kraus had even testified about
 those 11 MDD patients.

6 What exactly did Dr. Healy fly all the way back here
7 to say about these 11 patients? Well, he said some of them
8 might possibly have akathisia. But why didn't they just ask
9 Dr. Kraus? He's the one who reviewed the case files.

They brought Dr. Healy here to say that patients myself might have akathisia. What did he base it on? He sure didn't show you any evidence. He didn't show you a single document to support it, and he admitted that he not reviewed the case report forms like Dr. Kraus did.

Mr. Davis had to get up and go get Dr. Healy's notes
from him, and when he saw those notes, you saw that Dr. Healy
didn't note akathisia for any one of those 11 patients.

And what else did Dr. Healy claim? He said he found 19 12 suicide attempts that GSK didn't report. That's a pretty 20 serious claim. And when he made that claim, I thought, "I sure 21 hope Dr. Healy has something to back that up with." But he 22 didn't show you any evidence when Mr. Wisner was questioning 23 him; none. He didn't even bring it with him.

24So, we had to go and find the 12th patient, and we25did. And Mr. Davis showed it to you. It was this document

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1 that's on the screen. There's a good reason Dr. Healy didn't 2 show this to you, because it doesn't support his claim at all. 3 This wasn't a suicide attempt. The experts who classify these 4 events said, no, it's clearly in that column. 5 You can see for the 11 real suicide attempts, the 01:51:16 6 column says "yes." For Dr. Healy's supposed 12th, it says "no." 7 Plaintiff tried to fool you at the very end of this 8 9 case. The plaintiff tried to trick you into thinking GSK 10 missed something and failed to report something, but clearly 01:51:33 11 GSK did not. The document proves GSK submitted this event in 12 its analysis, that it was carefully analyzed by experts at 13 Columbia University, and it was determined not to be a suicide 14 attempt. 15 It's an example of what Dr. Healy and the plaintiff 01:51:48 16 has done all throughout the trial, to make a claim but not to

17 show you the evidence to back it up. And we then come behind
18 them, we show you the evidence, and you can see for yourself
19 what the plaintiff claims is not true.

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Let's talk about Dr. Healy again for a minute. He talked a lot, he told a lot of stories, but he did say one thing that was accurate, it's important to be looking data from all the different sources that you can.

24 But what data, what scientific evidence did Dr. Healy 25 bring you to show that Paxil causes suicide in adults? The

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	1	first study he talked about was Juurlink. Mr. Rapaport
	2	mentioned it briefly, but what he didn't mention is that the
	3	FDA knew all about Juurlink when it issued its class labeling.
	4	You recall it was about patients in Canada over
01:52:42	5	age 65. And let's look at what Dr. Juurlink and his coauthors
	6	wrote, they said:
	7	" many suicides during the first month of
	8	treatment likely result from depression itself
	9	rather than an adverse event of treatment."
01:52:57	10	And they also said that:
	11	" the actual risk due to suicide due to
	12	antidepressant is probably far lower."
	13	As Dr. Gibbons explained, the FDA's 2006 analysis did
	14	not replicate Dr. Juurlink's finding, but instead found that
01:53:23	15	the medications not only do not increase the risk in patients
	16	over 64, but actually have a significant protective effect of
	17	preventing suicidal thoughts or behavior.
	18	In fact, Mr. Wisner accidentally proved that the
	19	Juurlink article doesn't show paroxetine causes suicide. He
01:53:39	20	asked Dr. Healy if the Juurlink article would refute GSK's
	21	statement that no study has ever shown paroxetine causes
	22	suicide, and Dr. Healy said he didn't know because the article
	23	has no paroxetine-specific data.
	24	Dr. Healy also talked about his own Healy/Ferguson
01:53:58	25	study, but like Juurlink, it had no specific information on

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1 paroxetine, it's all SSRI data.

So when it comes to the plaintiff's burden of proving
paroxetine causes suicide, these all SSRIs studies with no
paroxetine findings are of no help to the plaintiff. They're
more white noise.

But even if you looked at all SSRIs together, the
FDA's analysis shows no association between SSRIs and suicidal
thoughts or behavior, which was the primary analysis or
suicidal behavior alone which was the secondary analysis.

Dr. Healy also cherry-picked the FDA and GSK analysis.
He only showed you the secondary findings that he thought
helped the plaintiff. He did not show you the findings on the
main questions that the FDA and GSK were studying.

Dr. Healy did not bring you a single piece of evidence
that paroxetine causes suicide in adults, much less in adults
over the age of 24, but he did make a key concession, he said
the group who had been of particular concerns in terms of
people who are depressed have been middle-aged men in their
40's, 50's, and 60's. He agreed that this was a group more at
risk for suicide.

With Dr. Healy it was mostly white noise. He spent
days talking about things that happened before 2004.
Everything that happened before 2004 is white noise in this
case, ladies and gentlemen. It had no impact on the paroxetine
label that this case is all about. That entire first board

	1	that Mr. Rapaport showed you was white noise. Dr. Healy spent
	2	a lot of time on the run-ins, but the run-in issue was closed
	3	forever in 2003 when GSK did its reanalysis. The run-in issue
	4	has nothing to do with the 2005 label, let alone the labeling
01:55:53	5	after the 2006 GSK and FDA analysis.
	6	Now, Mr. Rapaport said that GSK slipped the run-in
	7	issues by Dr. Brecher, that he somehow seems to have missed the
	8	run-ins. Ladies and gentlemen, FDA knew about the run-ins from
	9	the start and we showed you that evidence.
01:56:11	10	Can we pull that up.
	11	(Brief pause).
	12	MR. BAYMAN: I'm going to show it to you again very
	13	quickly. Here's what here's Dr. Brecher's clinical review,
	14	and here's what he said:
01:56:26	15	"two out of the 5 suicides occurred during
	16	the run-ins."
	17	Dr. Brecher knew about the run-ins. Dr. Brecher did
	18	the same calculations in his '91 report as GSK did in its 1991
	19	analysis. GSK provided that information to the FDA. GSK put
01:56:43	20	it in its own 1991 analysis, and GSK provided it to the FDA.
	21	Dr. Brecher knew about the run-ins.
	22	We also showed you documents demonstrating that FDA
	23	knew that suicide attempts were being coded as emotional
	24	lability.
01:56:58	25	Can we pull one of those up, Mr. Holtzen.

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(Brief pause).

2 MR. BAYMAN: We showed you a bunch of these with Dr. 3 Healy and also with Dr. Kraus. GSK clearly told the FDA that 4 suicide events were being coded to the preferred term of 5 emotional lability.

And you heard some discussion about a coding
dictionary. Dr. Kraus testified clearly that the coding
dictionary GSK used was not COSTART but rather was a
COSTART-base coding dictionary called ADEX, it did not have
"suicide attempt" as the preferred term. No coding dictionary
was brought in. That claim was never refuted.

12 Now, the plaintiff claims that GSK's analysis in 1991 13 was improper and that it showed some kind of a violation of 14 some mysterious regulation that they never showed you. They 15 never showed you a single document where FDA said GSK's 16 analysis was wrong. Where was the evidence that the FDA 17 disagreed with how the analysis was done in 1991? The only 18 analysis is Dr. Brecher did his analysis the same way as GSK 19 did, and that's because as Dr. Kraus told you, the FDA in those 20 days wanted all the data, from all phases of the trial, from 21 the run-ins to the events that occurred in uncontrolled trials 22 or extension phase when there was no placebo arm.

Dr. Kraus never said that including the run-ins was inappropriate, because that's what data the FDA wanted. But Dr. Gibbons and Dr. Kraus explained that the way the

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plaintiff's experts analyzed the data from the NDA is just
 plain wrong. They both said it's scientifically improper to
 include uncontrolled paroxetine events.

If we could pull that slide up.

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(Brief pause).

6 MR. BAYMAN: You remember this slide (indicating). 7 I'm not going to belabor it. The plaintiffs want account 8 events that occurred during the run-in, they want to take them 9 out, but they want to count events that occurred during the 10 extension phase when there's no placebo to compare against. 11 They want to count events from uncontrolled trials, again no 12 placebo. They want to count events from open-label studies 13 which are not blinded and don't have a placebo arm. They want 14 to count events from active controls. They don't want to count 15 the best data. They don't want to count the data, head to 16 head, looking at just the controlled portions of 17 placebo-controlled trials.

And you remember what Dr. Gibbons said, that if one of his students presented the kind of analysis the plaintiff's experts did, he'd tell them to go pursue a career in the legal profession.

In 2003, GSK did its reanalysis. It's apples to apples, looking only at the controlled portions of the placebo-controlled trials where plaintiff say those trials show a risk. Dr. Kraus, Dr. Rothschild, and Dr. Gibbons, all

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Mr. Wisner was guick to argue that the analysis done

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1 explained to you that it showed no difference between 2 paroxetine and placebo. And if you think back, the plaintiff 3 didn't challenge any of them on that point.

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5 by GSK and FDA in 1991 wasn't appropriate, but did you hear him 6 say the apples to apples reanalysis that GSK did in 2003 was 7 not appropriate? Did you hear him say the results of that 8 analysis were not reliable? No. And when they asked Dr. Dunbar in 2005, if he'd do some kind of correction to his 9 10 paper, he said no, because the reanalysis had already been 11 done.

12 There's no disputing it, GSK followed the same 13 analysis that the FDA later used in 2006, looked only at the 14 placebo controlled portions of placebo-controlled clinical 15 Dr. Ross confirmed that was the approach the FDA uses. trials. 16 He told you since 2004, FDA looked at randomized, double-blind 17 placebo-controlled trials for this analysis, and he told you 18 the FDA has never done anything other than look at those kind 19 of trials.

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So the plaintiffs are asking you to do an analysis 21 that the FDA would never do, but if you apply simple, basic 22 scientific principles, the answer is clear, there is no 23 increased risk. There is no increased risk, there was none in 24 1991, there was none when the data was reanalyzed looking 25 apples to apples in 2003, and there was none in 2006.

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20 The argument that paroxetine causes akathisia which 21 then causes suicide, is more white noise. Dr. Healy told you 22 that suicidal events -- most suicidal events that occurred 23 during the first 30 days of starting medication. We show you 24 there was no pattern in the MDD attempts.

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He told you relatedness assessments somehow support

1 When you include the noncontrolled portions, the 2 run-ins, the open-label extensions, the data from the other 3 kinds of trials, Dr. Kraus, Dr. Gibbons, Dr. Rothschild, Mr. 4 Davies, Dr. Dunbar, all said the same thing, it doesn't matter, 5 there is no increased risk.

6 Dr. Healy told you a lot of things. We showed you, he 7 was wrong. He told you suicides on Paxil are more violent. We 8 showed you that 8 of the 11 MDD suicide attempts were by Even Dr. Healy's own notes on Thursday showed these 9 overdose. 10 were overdoses. Dr. Kraus explained there was no evidence to 11 support Dr. Healy's conclusion from the clinical trials.

12 Dr. Healy used the board of suicide patients to claim 13 that 16 of the suicides were violent. That's not science. But 14 even if he's right, that doesn't tell us anything about whether 15 the suicides on Paxil or paroxetine are more violent than 16 suicides in general. Again, use your common sense.

17 He showed you that -- he told you that akathisia makes 18 more people on paroxetine suicidal. We showed you that none of 19 the 11 MDD patients had signs of akathisia.

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closing argument - by Bayman

	1	his theory of causation. We showed you that was not true in
	2	the 11 patients. Dr. Kraus told you GSK's analysis showed more
	3	relatedness on placebo than on Paxil. Relatedness assessments,
	4	like a lot of those 13 ways GSK hid the suicide signal
02:03:29	5	according to Dr. Healy, are just white noise.
	6	Now, you will recall that plaintiff's counsel showed a
	7	board with Dr. Kraus and also Dr. Healy about patients who
	8	committed suicide during the uncontrolled Paxil clinical
	9	trials. I wish I could bring in all the people whose
02:03:50	10	lives have been saved by Paxil. All the depressed people in
	11	the 200-plus clinical trials
	12	MR. WISNER: Objection, Your Honor.
	13	THE COURT: Proceed.
	14	MR. BAYMAN: who didn't attempt or didn't commit
02:03:57	15	suicide in those trials.
	16	And remember what Dr. Kraus explained: If you do, for
	17	example, a study of cholesterol medicine with people with very
	18	high cholesterol, you're going to expect to see some heart
	19	attacks in those clinical trials. The same is true with
02:04:15	20	clinical trials of people with psychiatric illnesses, if you do
	21	enough study you can expect to see some suicides, it's part of
	22	the underlying disease.
	23	Dr. Kraus told you he wasn't surprised that there were
	24	22 suicides in the clinical trials. In fact, he said he was
02:04:30	25	surprised there weren't more given how many clinical trials GSK

had conducted with patients with serious psychiatric illnesses,
 but he told you each one of those suicides mattered and each
 one was reported to the FDA.

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4 Now, we brought you Dr. Gibbons. He's not an 5 professional witness. He's not a business partner with the 6 He's an expert biostatistician at the University of lawyers. 7 And he told you his opinion that the SSRIs in Chicago. 8 general, and the paroxetine in particular, do not increase the risk of suicidal thoughts or behavior or completion; if 9 10 anything, they decrease the risk. That's the same conclusion 11 that the FDA made in 2007.

And Dr. Gibbons said he looked at clinical trial data and he looked at observational studies, clinical trial data being the gold standard. He told you how FDA requested all the antidepressant company makers submit their data and combine them together to create the largest most representative and high quality dataset that could be used to look at this question.

And it's undisputed that the FDA used the largest,
most robust set of randomized placebo-controlled clinical trial
data by anyone, ever, looking at the issues about whether these
medications cause or increase the risk of suicide.

He showed you there was no increased risk on paroxetine on the most important endpoint the FDA studied, the primary endpoint, nor was there an increased risk in all the

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SSRI group on either endpoint or in age 21 to 64. There was
 one finding on paroxetine, the secondary endpoint, and he
 explained that the FDA did well over 150 statistical
 comparisons, and when you do that, occasionally you will get a
 statistically significant result.

6 That's why FDA said, any findings on specific 7 medications must be discounted, but when asked whether the 2.76 8 finding for paroxetine on the secondary endpoint showed an 9 increased risk of suicidal behavior, he said that would be a 10 scientifically indefensible statement.

He talked about the observational studies, I'll
mention them briefly. The Simon paper, which found that the
risk of the suicide attempts was greatest in the month prior to
initiation of therapy as opposed to initiation.

That's important for two reasons:

16 First, it proves people don't suddenly get suicidal or17 more suicidal when they get the medication.

Second, this shows that the first 30 days of treatmentyour risk goes down, not up.

Dr. Gibbons walked you through his opinions, and he showed you the data to back them up. He showed you this chart, which I think you'll remember (indicating). But you don't need Dr. Gibbons or anyone else to explain what your eyes can see: The suicide attempts that drove the MDD finding in GSK's 2006 analysis are clustered in the young adult patients, that area

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in blue (indicating). Once again, this is just common sense.
In patients in Mr. Dolin's half of this chart, there were two
attempts on paroxetine and one on placebo. That's exactly what
you would except to see if there's no increased risk since this
patient population had roughly twice as many patients on
paroxetine as on placebo.

Dr. Gibbons was very clear, look at -- when you look
at all of the data, as Dr. Healy says you should do, there's no
evidence that paroxetine increases the risks of suicidal
thoughts or behavior in adults like Mr. Dolin.

11 Which brings us lastly to Dr. Ross. Dr. Ross refuses 12 to say Paxil causes suicide. It was really odd, in his report 13 he said there was an association, and he said "causation" and 14 "association" were different. And then he came in here, and he 15 first said that his opinion was that paroxetine causes suicide, 16 but when I asked him a few minutes later he said something odd, 17 he said he's not saying Paxil causes suicide, he says it 18 induces it. But then Dr. Ross, the so-called regulatory 19 expert, said "cause" has a regulatory definition but "induce" 20 does not.

So, the regulatory expert won't use the term with the regulatory definition, the term "cause." Dr. Ross would not say Paxil causes suicide. The plaintiff's expert they brought in, that they needed to prove the point, said he wouldn't even say it.

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	1	So, let's get back to the question we're answering,
	2	whether Paxil causes suicide in adults. The FDA has said "no,"
	3	many scientists that have researched this issue said "no," GSK
	4	and Dr. Kraus have thoroughly researched and answered "no," and
02:09:16	5	even Dr. Ross will not say "yes." All you're left with, ladies
	6	and gentlemen, is the plaintiff's empty verdict form
	7	plaintiff's empty words of the plaintiff's experts.
	8	The overwhelming evidence on this question about
	9	whether the scientific evidence proves paroxetine causes
02:09:34	10	suicide in adult patients in adults over 24 is a clear "no."
	11	And since the plaintiff cannot meet her burden of
	12	proving Paxil causes or paroxetine causes suicides in adults
	13	over age 24, this means your verdict must be against the
	14	plaintiff.
02:09:51	15	Now, that brings us to the second question, and I'm
	16	going to be a lot briefer in this section: Did GSK communicate
	17	with FDA and doctors about a possible risk of Paxil and suicide
	18	in adults over 24.
	19	Remember what the plaintiff's claim is, the paroxetine
02:10:07	20	label is inadequate because it does not say it can cause adults
	21	over 24 to commit suicide. So, when it comes to the warning
	22	for paroxetine, the plaintiff must prove that the label could
	23	have and should have paroxetine causes suicide in adults over
	24	24, but as we're about to see, GSK and the FDA have never
02:10:26	25	considered including that statement in the label.

closing argument - by Bayman

1 You've heard the labeling story over many days in this 2 trial, but no one disagreed that a label must be updated to 3 keep up with the evolving science and knowledge about a medication, because science evolves. But we can boil the 4 5 labeling story down to a pretty simple story that can be told 02:10:46 6 in three acts: 7 Act One, 1992 to 2006, when Paxil was first approved 8 in 1992 there was to evidence of an increased risk of suicidal 9 thinking or behavior. The FDA did a thorough review of the 10 science at the time and even held an advisory board meeting. 02:11:02 11 Dr. Ross told you that FDA had to approve all the 12 labeling. Here's what he said: 13 "... the first label described the risk of 14 suicide that accompanies all antidepressants 15 . . . " 02:11:13 16 and that language didn't change for a long time, 17 because there was no scientifically reliable evidence to 18 support it. In the meantime, GSK made repeated submissions to the 19 20 FDA. You saw those admissions on the earlier slides, 02:11:26 21 submissions for new indications, death reports, suicide 22 reports, annual reports involving serious adverse events. FDA 23 had no evidence to support a label change and GSK didn't 24 either. 25 Then in 2004 there was new information about pediatric 02:11:42

patients. And in conjunction with that, FDA required new
 language be added about adults as well.

FDA issued class labeling. It took over this issue,
and here's what it said, you've seen this many times
(indicating). This was part of the new clinical worsening and
suicide risk section (indicating).

Now, the plaintiff's experts have said this is disease
management, but this is speaking directly to observing patients
taking SSRIs for emerging suicidality. The FDA class labeling
in 2004 also told families and caregivers what they should be
told.

But importantly in 2005, FDA added this language, which talks about all the symptoms that may represent precursors to emerging suicidality, such as akathisia, anxiety, agitation. As we can see in this slide, this language has never gone away (indicating). It was in the label in 2005, it was there throughout the time Mr. Dolin was taking paroxetine, it's in the language today.

As we also saw, GSK added precaution for akathisia in 202005. Then GSK did its 2006 analysis. And as I said, GSK did 21what a responsible, reasonably prudent company would do, and 22that is it added the new important findings to the label. And 23here's what the label said, it did not say "cause" because 24that's not what the analysis showed, but it did say there was 25some risk and the risk extended to all ages.

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1 Dr. Ross admitted this. GSK made the change as a 2 change is being effected or a CB supplement, but Dr. Ross said 3 something important, the FDA must still approve it. 4 FDA did not object to this language and GSK 5 implemented it, but FDA never approved this language because it 02:13:39 6 was doing its own analysis, and that stayed in the label for 7 roughly a year. Then came Act Two, in 2006 and 2007, the FDA took 8 9 control. It completed its analysis and it said it wanted more 10 class labeling. Here's the labeling the FDA required 02:13:56 11 (indicating). You have seen this a bunch during this trial. 12 On May 2nd, 2007, nearly ten years ago, FDA wrote to GSK and 13 said, here's the language you must use, and even Dr. Ross 14 agreed, must be used. 15 But GSK still wasn't sure what this meant for the 02:14:18 16 Paxil-specific language that was already there, could GSK leave 17 that in or did they have to take it out. GSK wanted to keep, 18 as Dr. Kraus said, because they felt it was complimentary to 19 the FDA's language and it was additional information about 20 Paxil or paroxetine the prescribers might find useful, but when 02:14:35 21 it came to the risk profile of paroxetine or Paxil, FDA and GSK 22 were on the same page, neither GSK's language that had been 23 there nor FDA's proposed class language said there was an 24 increased risk of suicide in adults over age 24. 25 But GSK still wasn't sure what it was supposed to do 02:14:54

with the Paxil-specific language, so it did what your common
sense would tell you to do, it asks FDA. GSK asked, "do we
have to replace our language with yours?" And the FDA said,
"yes." And then GSK went back to the FDA again and again and
again, and FDA told GSK it could not include the Paxil-specific
language. It wanted the class language and the FDA has the
final say on what goes in the label.

Now, Dr. Ross claimed there was no evidence that the
FDA would've stopped GSK from putting the Paxil-specific
language in the label, but as this slide show, the FDA made its
position clear.

12 But one thing I want to be clear on, GSK was not 13 asking FDA to include the Paxil-specific language because it 14 thought the label would be false or misleading without it. GSK 15 was not asking FDA to include the Paxil-specific language 16 because it thought the FDA's language did not provide enough of 17 a warning. As Dr. Kraus said, the results were what they were, 18 and GSK wanted to provide doctors the information so that they 19 could make informed decisions about their decisions.

But make no mistakes, ladies and gentlemen, none of the labeling language that GSK and FDA were debating in 2007 said what the plaintiff thinks it should say, which is Paxil causes suicide in adults over 24.

Now, you might wander why is the plaintiff making abig deal in this case about a meeting that never happened?

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Plaintiff made it very clear that the language GSK was seeking
 to include was not adequate. Dr. Ross said that. But even Dr.
 Ross concedes that if GSK had had this meeting with the FDA, he
 doesn't know what the FDA would have done in the meeting.

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5 But why are we focusing on the meeting? Why does 6 plaintiff care whether GSK's language was in or out if GSK's 7 language still was not good enough because it didn't say it 8 causes suicide in adult patients? I'll tell you why, because 9 they're trying to trick you again. They're trying to create a 10 false narrative that if GSK had had this meeting, FDA would've 11 said "put in the language that Paxil causes suicides in adults" 12 over age 24." And they're creating this false narrative 13 because they know they can't prove what they need to prove, 14 that GSK should've proposed a label that says Paxil causes 15 suicide and that the FDA would've approved it.

But use your common sense, ladies and gentlemen. If FDA wasn't going to approve the Paxil-specific language in the label that didn't say Paxil causes suicide, is it really believable for the plaintiff to claim the FDA would've approved one that said it does cause suicide? That would've been directly opposite to what the class labeling says.

And that highlights the loudest white noise perhaps in the entire case, Dr. Ross's label where he identifies all the places GSK could have put its warning language, it's white noise because we're talking about language that doesn't say

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closing argument - by Bayman

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1 what the plaintiff claims. You heard it from Dr. Ross's mouth,
2 he said the language that -- he said the language that GSK was
3 asking to keep in, which was "no increased risk in patients
4 age 25 to 64" would make the labeling more misleading, not
5 better.
6 So why is the plaintiff trying to convince you that

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7 GSK should've asked for this meeting? Because they know they
8 can't prove what they need to prove. It's a trick to make you
9 think that if you agree with them about the meeting and the
10 Paxil-specific language, you should find for them.

The issue was, ladies and gentlemen, whether there was
scientific evidence to support the label that says Paxil causes
suicide in adult patients over 24, and there wasn't. Never
was, never has been.

And this trick explains the word games that Dr. Ross played when I asked him about his deposition testimony. Remember at his deposition he refused to tell us where the additional warnings should go in the label. We said, "you wouldn't tell us where it should go," and he said, as you see on the screen:

> "... you asked about "should go" not "could go" ..."

The reality is, the language the plaintiff wants that paroxetine causes suicide in adults over age 24 couldn't go anywhere in the label because there's no signs to support it, 1 and the FDA wouldn't approve it.

When GSK finally submitted the labeling change with
the class language and without the Paxil-specific language, the
FDA ultimately approved it. And Dr. Ross agreed, the FDA
ultimately must approve prescription drug labels.

The FDA implemented class labeling in all the sections of the label where the suicide risk might be discussed, all the black box warnings, precautions, information for patients.

9 And Dr. Ross told you that by approving it, the FDA
10 was saying that it was not false or misleading. Dr. Ross
11 explained the sections of the label, and he told you where the
12 suicide warnings could go, and that's exactly what FDA did in
13 its class labeling.

Now, you've heard in this case, and you'll be
instructed tomorrow, that the federal regulations require a
warning when there's reasonable evidence of an association.
Since before Mr. Dolin was ever prescribed Paxil, the label
contained a warning about an association between paroxetine and
suicide in adults of all ages.

GSK didn't wait for causality to be proven, something
that still has not happened to this day, to warn about suicide.
There's an association, which all the plaintiff's experts agree
does not equal causation and the label describes that.

You heard Dr. Kraus say he did his best to describethe risk accurately. So GSK has met its obligations.

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closing argument - by Bayman

As I mentioned to you earlier, it's been 10 years 1 2 since the FDA announce its class labeling. Ask yourself, of 3 all the evidence that plaintiff has presented in this case, 4 what didn't the FDA know when it implemented the class labeling 5 in 2007? Dr. Healy said he was at the FDA advisory committee. 02:21:05 6 Obviously, knew all the data from its own analysis, and knew 7 GSK's analysis, it knew the articles, and certainly knew about 8 the white-noise issues like run-in events and the coding events to emotional lability. And fact is, FDA had all the 9 10 information plaintiff thinks matters when it issued its class 11 labeling, and the FDA did not conclude that the labeling should 12 say Paxil causes suicide in adults over age 24. As I said before, what this comes down to is the 13 14 plaintiff not agreeing with the FDA's analysis and the FDA's 15 decision.

> 16 And just to be clear, before Mr. Rapaport gets up at 17 the end and says we're pushing all the responsibility to the 18 FDA, let me be clear, GSK took responsibility for the label. 19 It reached the very same conclusion as the FDA, GSK does not 20 believe that paroxetine causes suicide in adults over age 24 21 and the data does not demonstrate that.

22 It has never believed that, it has never concluded 23 that, it has never believed the label should say "Paxil or 24 paroxetine causes suicide in adults over age 24," and it's 25 never asked the FDA for permission to put that in the label.

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1 This is not a case about what GSK did in the 1980's or 2 1990's, a decade or more before Stewart Dolin ever took Paxil. 3 It's about the science in 2005 and 2006 when the labeling 4 language Dr. Sachman relied on to prescribe paroxetine to Mr. 5 Dolin was written, and that science does not support a warning 02:22:35 that Paxil causes suicide in adults over 24. 6 7 So, on the point the plaintiff must prove that Paxil's 8 labeling was not adequate, the plaintiff has failed to meet her 9 burden of proof, and once again, your verdict must be against the plaintiff. 10 02:22:52 11 I'm going to sit down now and let Ms. Henninger talk 12 to you about the first and the fourth questions. 13 Thank you for your time and for your attention. 14 THE COURT: All right. Thank you, Mr. Bayman. 15 Ms. Henninger. 02:23:05 16 Yes. Your Honor. MS. HENNINGER: 17 CLOSING ARGUMENT ON BEHALF OF DEFENDANT 18 MS. HENNINGER: May it please the Court. Counsel, Mrs. Dolin. 19 20 Ladies and gentlemen of the jury, how are you this 02:23:09 21 afternoon? We're getting there. I promise I have my allotted 22 time, and then Mr. Rapaport has a little bit of time left, and then you will get this case tomorrow morning. So I'm sure 23 24 you're glad to hear that. 25 And I want to start where Mr. Bayman left off and talk 02:23:26

to you about the third hurdle, the third thing that plaintiffs
 must prove in order to prevail in this case.

3 And plaintiff must prove that Dr. Sachman was not 4 aware that the risk of suicide may extend beyond the age of 24. 5 And I want to talk about that, and I really want to talk about the evidence and the testimony, because even Mr. Rapaport 6 7 mentioned today that that is something they have to prove. And 8 tomorrow when you hear the Court's instruction, you are going to get this instruction, it's the duty to warn instruction. 9 10 And this instruction says:

"The drug involved in this case can only be
obtained by a prescription from a physician.
For this reason, the defendant has a duty to
warn only the physician of the risks which it
knew or in the exercise of ordinary care should
have known. The defendant has no duty to warn
the consumer directly."

That is why we're going to analyze the issue as to what Dr. Sachman knew, ladies and gentlemen, because Dr. Sachman is the only physician that the evidence has shown has ever prescribed paroxetine to Mr. Dolin.

So let's start where we started. Let's begin my closing where we started almost -- or a little bit over 5 weeks ago. You're going to recall that Mr. Rapaport in his opening statement said that you'll also hear evidence that at the time

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closing argument - by Henninger

1 this prescription was made, that Dr. Sachman had no idea that there was an increased risk of suicide for some patients that 2 3 take Paxil. That's where he started almost six weeks ago. 4 And you'll recall that big board that was taped up 5 there to the witness chair, that's where he started today as 02:25:14 well, he said Dr. Sachman would never have prescribed this 6 7 medication if GSK did what it should have done. Well, I want to walk through this evidence and I want 8 to focus on the testimony of Dr. Sachman, because the evidence 9 10 shows that Dr. Sachman knew the risks and he told Mr. Dolin 02:25:37 11 exactly what plaintiff's claim should have been told. 12 So let's look at the evidence in this case, ladies and 13 gentlemen. The evidence is that Dr. Sachman knew. His 14 testimony, while he was sitting in this chair, was -- the 15 question was: 02:25:57 "And before you wrote the last prescription for 16 17 paroxetine to Stewart Dolin, you recognized that 18 the increased risk of suicidal thoughts or 19 behavior was not limited to patients who were 24 20 or younger, true?" 02:26:11 21 His testimony under oath before you, ladies and 22 gentlemen, was "true." That should not the analysis right 23 Don't need anymore. Plaintiff has failed to meet their there. burden of proof. 24 25 But there's more, and I'm going to go through it. 02:26:29

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As

		closing argument - by Henninger 4378
	1	you know from your experience with us the last 5 weeks, the
	2	attorneys leave no stone unturned. So let's look at some more
	3	testimony. Let's look at the evidence as to what Dr. Sachman
	4	told Mr. Dolin:
02:26:47	5	" and after you reinitiated paroxetine for
	6	him you, in 2010, you explained to him that
	7	information because what you knew about Paxil or
	8	paroxetine and that patients who took that
	9	medication may be at an increased risk for
02:27:03	10	suicidal thoughts or behavior, true?"
	11	Testimony under oath in that chair, "true." That was
	12	what Dr. Sachman said before you, ladies and gentlemen.
	13	So now, you may ask yourself, well where did Dr.
	14	Sachman get this information, because plaintiff claims nobody
02:27:22	15	knew. Well, where did he get this information? Well, the
	16	evidence shows you that he got this information from
	17	GlaxoSmithKline, my client. And how did he get it? He got it
	18	from the labeling, but he also got it from Dear Healthcare
	19	Provider letters. All of these things are in evidence, ladies
02:27:40	20	and gentlemen, and we're not going to read through them. And
	21	I'm sure you're very happy about that, but I prepared this
	22	little timeline to kind of show you, outline for you the
	23	chronology here.
	24	He gets a Dear Healthcare Provider letter in May 2004,
02:27:52	25	in February of 2005, his first prescription of paroxetine to

	1	Mr. Dolin is October 3rd, 2005. And then he gets another Dear
	2	Healthcare Provider letter in May 2006, and that Dear
	3	Healthcare Provider letter was the one that contained this
	4	Paxil-specific information that was in the 206 label. We're
02:28:18	5	going to talk about that here in a second. So that's the
	6	information that Dr. Sachman had, and he got it from my client.
	7	So now let's look at what he did with this information.
	8	With regard to the 2005 Dear Healthcare Provider
	9	letter, this was Dr. Sachman's testimony:
02:28:34	10	"When you started Mr. Dolin on the medication
	11	paroxetine, you talked with him about the
	12	information that's in the February 2005 Dear
	13	Healthcare Provider letter, correct?"
	14	"Yes."
02:28:48	15	"You also did that with Mr. Dolin when he went
	16	back on paroxetine in 2010, correct?"
	17	He was reminded of them:
	18	"Yes, yes you did?"
	19	"Yes."
02:29:08	20	"And you also talked with Mrs. Wendy Dolin
	21	about the information that's in the
	22	February 2005 Dear Healthcare Provider letter,
	23	correct?"
	24	"Yes."
02:29:21	25	So he talked with Mr. And Mrs. Dolin about the 2005

	1	Dear Healthcare provider letter. Well, what about the 2006
	2	Dear Healthcare Provider letter? Well, the evidence again
	3	there is that Dr. Sachman not only got it, but he told Mr.
	4	Dolin about that information, about the Paxil-specific language
02:29:32	5	that GSK put in the label.
	6	And you see right here the testimony:
	7	" and at the time that the May 2006 Dear
	8	Healthcare Provider letter and revised labeling
	9	was read and reviewed by you, Mr. Dolin was
02:29:45	10	still receiving paroxetine prescription from you
	11	in 2006, correct?"
	12	Dr. Sachman says, "yes."
	13	"And you most likely discussed with Mr. Dolin
	14	these revisions to the warnings of paroxetine
02:30:00	15	and Paxil, correct?"
	16	"Correct."
	17	So, this is the labeling that came with the Dear
	18	Healthcare Provider letter in 2006 and ended up in the label.
	19	And you see that Dr. Sachman continues to say that he discussed
02:30:13	20	this labeling with Mr. Dolin, he told him about the risk of
	21	increased suicidal thoughts or behavior, and he specifically
	22	did not limit that risk to 24 and younger.
	23	Plaintiff cannot meet their burden of proof, ladies
	24	and gentlemen. The evidence is that Dr. Sachman knew the
02:30:33	25	information, and he told Mr. Dolin the information. So, when
1 Mr. Rapaport argues to you that only if Dr. Sachman had known 2 about the 11 patients, or the washouts, or run-ins, or whatever 3 data he may claim, the simple fact of the matter is that Dr. 4 Sachman had the information and he provided it to Mr. Dolin and 5 Mrs. Dolin.

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So, let's look at the 2010 labeling. You'll recall 6 7 that there's a list here of the following symptoms, such as 8 anxiety, and agitation, and panic attacks, and things even including akathisia. And a lot of plaintiff's experts came in 9 here and said, "well, that's just all disease management 10 11 stuff." Well, that's their opinion, but Dr. Sachman testified 12 that this isn't disease management to him. To him, you'll see 13 at the very bottom, that this statement is a statement of the 14 most common side effects seen with these drugs, SSRIs, not 15 disease management but side effects that Dr. Sachman was aware 02:31:32 16 of and side effects that he told Mr. Dolin about.

> 17 There's more testimony regarding what Dr. Sachman told 18 Mr. Dolin, and this is from 2010. It says:

"... in 2010 you told him to look out for signs 19 20 such as agitation, increased restlessness or 02:31:52 21 insomnia, panic attacks, worsening depression or 22 suicidal thoughts or behavior." 23

And he said, "right."

24 He did that in 2010, and he did not, if you read 25 down, he did not limit that to patients 24 and younger. Dr.

		closing argument - by Henninger 4382
	1	Sachman knew and Dr. Sachman told.
	2	One more slide as to what Dr. Sachman knew. If you
	3	focus just on the last Q and A's down at the bottom:
	4	" one of the potential side effects that Dr.
02:32:27	5	Sachman knew about included the worsening of
	6	depression or suicidal thoughts or behavior,
	7	right?"
	8	His testimony, "yes."
	9	"And you understood that at the time, at the
02:32:40	10	time you last prescribed paroxetine to Mr.
	11	Dolin?"
	12	"Yes."
	13	Plaintiff can't meet their burden of proof because
	14	Dr. Sachman knew and Dr. Sachman told.
02:32:53	15	And Dr. Sachman didn't limit his information to Mr.
	16	Dolin, because he also told Mrs. Dolin, as you have seen from
	17	the testimony. And Mrs. Dolin took the stand and never refuted
	18	that Dr. Sachman told her and told her husband all of the
	19	things that plaintiff has been claiming should've been told for
02:33:13	20	the last 5 weeks.
	21	So, the evidence shows that in 2010 that Dr. Sachman
	22	warned Mr. Dolin about the increased risk for suicidal thoughts
	23	and behaviors, and Dr. Sachman did not limit his warning to
	24	patients 24 or younger. Dr. Sachman knew and told Mr. And Mrs.
02:33:37	25	Dolin exactly what plaintiff has spent five weeks here claiming

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should have been told.

Now, you may ask yourself, well, if that's true, if
Dr. Sachman had all of the information, and if Dr. Sachman
warned Mr. Dolin, why did he, in response to questions for
plaintiff's counsel, say that he would never prescribe
paroxetine to Mr. Dolin if only he had known?

7 Well, the Court is going to instruct you as to the 8 testimony of witnesses, ladies and gentlemen. And it's your 9 decision, you are the triers of fact in this case, but you must 10 desired whether the testimony of each of the witnesses is 11 truthful and accurate, in part or in hole, or not at all. You 12 also must decide the weight, if any, you give to the testimony 13 of each witness. And one of the things you are to evaluate is 14 the interest, the bias, or the prejudice the witness may have.

7now, those words" bias" or "prejudice," those aren't bloated words in this context. They're asking you to examine to see if there's another reason for the witness's testimony.

So, what would potential bias be? Well, Dr. Sachman,
as you know, is a dear, dear friend of Mr. and Mrs. Dolin.
They've been friends since the 1990's. This is not your
ordinary doctor-patient relationship, ladies and gentlemen. In
fact, Dr. Sachman is here today to support the Dolin family.
They've been close friends.

24 When he testified, you recall he wore a tie and a belt 25 that belonged to Mr. Dolin. He talked about the relationship.

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In the 11-minute montage that you watched before plaintiffs 1 2 rested their case, there were numerous, numerous pictures of 3 the Sachmans on vacation with the Dolins. And there's nothing 4 wrong with that. They're close family friends, but that's 5 something you need to consider, ladies and gentlemen. 02:35:35 6 Now, another thing the evidence is biased in this case 7 on behalf of Dr. Sachman is the fact that he was treating Mr. 8 Dolin for free. Remember the testimony about the concierce's 9 practice he had, or the boutique practice, and the fact that Mr. Dolin didn't have to pay that fee. Well, Mrs. Dolin told 10 02:35:55 you that essentially means that he was treating him for free. 11 12 And you also remember this testimony from Dr. Sachman 13 being on the stand when he was asked: 14 "And you told Mrs. Dolin that you wanted to be 15 supportive and help her in any way that you 02:36:10 16 could with the lawsuit, and comply with anything 17 she wanted you to do as long as it was okay with 18 your malpractice carrier and attorney?" 19 And he said "true." 20 And then there was another question: 02:36:27 21 "And that also dealt with you signing a 22 declaration or sworn statement that the 23 plaintiff's lawyer, named Michael Baum, had sent 24 you, correct?" 25 And he said, "correct." 02:36:39

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There's nothing wrong with the fact that they're
 friends, ladies and gentlemen, but that's a fact that you need
 to consider in assessing the credibility of the witnesses and
 the changing testimony that you saw from Dr. Sachman.

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5 Here is an example of this changing testimony, because 6 he came into court and he testified that the 2010 labeling to 7 him, when being asked questions by Mr. Rapaport, was false and 8 misleading. Now, in considering this testimony, ladies and gentlemen, remember the facts how it's changed. 9 Before 10 stepping foot in this courtroom he testified, under oath, that 11 he was unaware that the Paxil-specific language from 2006 was 12 removed from the label in 2010 until after Mr. Dolin passed 13 away.

He was shown a number of statements that he made in his deposition in which he could not say if he looked at the 2010 labeling or when he had looked at the 2010 labeling.

Now, regarding the 6.7 number that Mr. Rapaport
mentioned that was all important, and if only Dr. Sachman had
known of the 6.7 number. Well, this is another example of the
change in testimony we saw in court.

Before Dr. Sachman came to court, he admitted that information not in the 2010 labeling was what he needed to know to make a decision on whether to prescribe paroxetine to Mr. Dolin, specifically the 6.7 number you see in the GSK statement on 2006 adult analysis.

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1 Now, on cross-examination he admitted that the 2 information from this analysis that GSK did in 2006 is what he 3 needed to know on whether or not to prescribe paroxetine to Mr. 4 Dolin. He then admitted that the 2006 Dear Healthcare letter 5 that he got in 2006 gave him the information he needed, ladies 6 Dr. Sachman knew the information, he got it and gentlemen. 7 from GSK, he told Mr. Dolin, and for those reasons plaintiff's 8 claim fails.

9 Now, there's one more thing to talk about and that's 10 just how sometimes actions speak louder than words, because 11 when Dr. Sachman testified, he went through great lengths to 12 say that if he knew there was any increased risk of suicide 13 with paroxetine, he never would've prescribed it for his 14 friend, never. But just days before he prescribed the 15 paroxetine, ladies and gentlemen, he prescribed another 16 medication, Levaguin. It's just an antibiotic, but in that 17 prescription labeling for Levaguin, it specifically says not 18 "increased risk" but it says "causes," that Levaquin can cause 19 suicidal thoughts or behavior.

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No one is here clamming that Levaquin led to Mr. Dolin's death, and do not take it that I'm suggesting that, but what I am suggesting is that Dr. Sachman said he would never have prescribed paroxetine if only he knew, but here he is prescribing another medication just days before with a stronger warning about suicide. Actions speak louder than words, ladies

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1 and gentlemen.

For those reasons, when you get to the first question,
which is liability, it's kind of a broad question, you should
find against the plaintiff.

for me to talk about, the last hurdle. And this hurdle

plaintiff must prove that paroxetine caused Mr. Dolin's death.

But, as you know, there's still one more general area

Now, plaintiff has the burden of proving all four of

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9 those hurdles we've shown you throughout our closing arguments,
10 but plaintiff has the burden to prove that paroxetine caused
11 Mr. Dolin's death, which is especially interesting given that
12 they spent less than ten minutes talking about Mr. Dolin in
13 their closing arguments. They have the burden of proving this
14 to you, ladies and gentlemen, and they have to prove it with

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evidence.

GlaxoSmithKline has no burden in this case. It is not
our burden to prove to you why Mr. Dolin committed suicide.
That burden, and that burden alone, rests with plaintiff.

So, this hurdle and this question is about Mr. Dolin.
Now, I want to talk to you about, before I talk about the
evidence much more, I want to talk to you about the fact that
in examining this question, that there's no disrespect meant
for the Dolin family. In this lawsuit, as you've heard, Mr.
Rapaport and the plaintiff are claiming well over \$30 million.
It is our duty to provide to you the information that shows why

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they haven't met their burden of proof in this case and not
 entitled to any damages. And we wouldn't be doing our jobs if
 we didn't look at the facts about Mr. Dolin.

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So, let's start with those facts, but first I want to talk about the plaintiff's burden, and her burden is to prove her case with evidence, not speculation, not guesswork, and not inconsistent evidence.

8 So, before we get into the facts of Mr. Dolin, let's talk about some of the general facts you've heard about 9 10 suicide, in general. And I'm not going to go through all these 11 with you, ladies and gentlemen, because you have this in front 12 of you, but Dr. Glenmullen got on the stand and he made a very 13 important point, because he said that, wealth, financial 14 status, the fact that you have a lot of friends does not make 15 you immune to suicidal thoughts or behavior. Being rich, being 16 popular, does not mean this can't happen to you.

Dr. Rothschild also added some interesting facts, and again I'm going to focus on the interesting facts related to attorneys, because Dr. Rothschild talked to you and told you that attorneys have the fourth highest rate of suicide amongst professions, and in the attorney profession suicide is the third leading cause of death, the third leading cause of death behind heart disease and cancer is suicide.

And the one thing that Dr. Glenmullen and Dr.
Rothschild agree on is that, most often than not, somebody sees

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this coming. The fact that the family or friends or colleagues
 say they had no clue this was coming, they're shocked by this
 result, that's a common phenomenon in suicide. People don't
 see it coming.

5 So, let's focus now on plaintiff's claim, what 02:43:32 6 plaintiff has to prove. And they have to prove that paroxetine 7 caused Mr. Dolin's suicide. You may remember this 8 demonstrative that Dr. Healy used (indicating). And in this demonstrative he said to you, from the stand, he said there 9 10 were three mechanisms, three mechanisms by which paroxetine, in 02:43:51 11 his opinion, can cause suicide. The first was an emotional 12 blunting, the second was psychotic decompensation, and the 13 third was akathisia.

Well, there's not a single witness who came in this
case and told you anything about Mr. Dolin having emotional
blunting, so that mechanism is gone.

17 Psychotic decompensation, nobody talked to you about18 psychotic decompensation.

So what's left? The only mechanism left is plaintiffs
have to prove that Mr. Dolin had akathisia, and that akathisia
was caused by his paroxetine, and that caused him to commit
suicide.

So I'm going to focus on akathisia for a minute.
Remember the DSM that doctors -- Dr. Glenmullen, I believe, and
Dr. Rothschild both used. There's a whole chapter in the DSM,

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	1	which is used by psychiatrists and psychologists, a whole
	2	chapter dedicated to medication-induced movement disorders.
	3	And within that chapter there is a definition for
	4	medication-induced acute akathisia. And the definition is
02:45:03	5	right there in front of you, but what's also interesting is in
	6	that chapter, in this DSM that psychiatrists and psychologists
	7	and even social workers use sometimes, according to Dr.
	8	Glenmullen, there's absolutely no mention, no mention of
	9	medication-induced suicide.
02:45:15	10	Now, Dr. Glenmullen came in and talked to you about
	11	why he thought Mr. Dolin had akathisia, but remember, Dr.
	12	Glenmullen had a different definition of akathisia outside the
	13	courtroom, one that he used in his book.
	14	Remember the patient named Ron that he described. And
02:45:33	15	he said that "Ron," and I'm not going to read the whole thing,
	16	but it was a very long narrative about how this individual
	17	could not sit still. And he says:
	18	" in medication-induced agitation the patient
	19	cannot, cannot escape the urge to move,
02:45:49	20	particularly move his legs."
	21	That is Dr. Glenmullen's definition of akathisia when
	22	he's not in court, but here in court he has the facts related
	23	to Mr. Dolin and that definition doesn't apply.
	24	So what's he do? He changes it and he says, "you
02:46:06	25	don't have to have constant movement. It can go one day and be

1	gone	the	next.
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Well, Dr. Rothschild talked about this, and he said, no, that's not true, it's always there. You remember the test that both Dr. Healy and Dr. Rothschild talked about, the Barnes scale, if you look at somebody for two minutes, you will know that they have akathisia because it's constant.

And you know, if there is such a test that both Dr.
Healy and Dr. Rothschild use, why didn't plaintiffs prove that
he had akathisia according to that test? Well, the answer is
because they couldn't, because there was no evidence of
constant movement in Mr. Dolin.

12 Now, I want to address one other important point about 13 akathisia, is that there is an inner component and an outer 14 component of akathisia. You know that the leg shaking and the 15 inability to sit still, that's the outer, and that's what you 16 can't stop, but there's also an inner component to akathisia. 17 But what's important in this, as Dr. Rothschild told you and 18 what's in the DSM, is you can't have inner akathisia without 19 some outer akathisia, they go together.

So, you need to have the outward signs. And because none of us are psychiatrists or psychologists, from my closing statement, I'm going to focus on the outward signs, because that's what common people can do, you can notice it. Back to what Dr. Rothschild says, you don't have to be a doctor to notice the outward signs of akathisia, so let's talk about

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them.

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	2	There's not a single medical record that mentions
	3	akathisia, pacing, or restlessness, no witness observed
	4	akathisia, and Mr. Dolin never complained of akathisia.
02:47:50	5	So three healthcare providers, Dr. Sachman, Ms. Reed,
	6	and Dr. Salstrom all testified they treated Mr. Dolin, they saw
	7	him, all of them saw him the week that he committed suicide.
	8	What was the number of them that came into court and testified?
	9	There were three. Out of those three who treated, who saw him,
02:48:13	10	who actually were involved in his care, how many of them
	11	diagnosed him with akathisia? And the answer is zero. How
	12	many of them told you that paroxetine caused Mr. Dolin's
	13	suicide? Zero.
	14	THE COURT: All right. Ma'am, we'll break now.
02:48:31	15	MS. HENNINGER: Okay.
	16	THE COURT: For our afternoon recess, ladies and
	17	gentlemen.
	18	Marshal, escort the jury, please.
	19	THE MARSHAL: All rise.
02:48:43	20	(The following proceedings were had out of the
	21	presence of the jury in open court:)
	22	
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	24	
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		closing argument - by Henninger 4394
	1	"Going back looking at going back through
	2	your notes, do you see anywhere where you
	3	documented that Stewart paced or could not sit
	4	still during a theory session?"
03:06:41	5	She said:
	6	"No, that never happened."
	7	And then the question was:
	8	"Would you have documented that?"
	9	And she said:
	10	"I might have, but I remember him, I remember
	11	those people who can't sit still and pace."
	12	So, reminding you where we left off before the break
	13	is, I'm looking at, in this argument, the outer signs of
	14	akathisia to see if anybody noticed the outer signs.
03:07:08	15	Now, Dr. Glenmullen admits Dr. Glenmullen admits
	16	that Mr. Dolin himself never reported akathisia. He looked
	17	through all the medical records and nowhere did he see Mr.
	18	Dolin reporting to his doctors or therapists, or anybody else
	19	in this case, statements along the lines that he felt like he
03:07:27	20	was jumping out of his skin.
	21	But we don't have to take my word for it or Dr.
	22	Glenmullen's words, we can look at Mr. Dolin's own words.
	23	In his 7/12/2010 questionnaire that he completes
	24	there's a question. You remember this questionnaire. We're
03:07:45	25	going to talk about it some more in detail:

closing	argument	-	by	Henninger
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		4395
	1	"Do you feel very jumpy and physically restless
	2	and have a lot of trouble sitting calmly in a
	3	chair, nearly every day in the past 2 weeks."
	4	Mr. Dolin circled "no." Those are his own words.
03:08:03	5	And let's look at what else he said about paroxetine.
	6	(Brief pause).
	7	MS. HENNINGER: It never fails that I will have
	8	technical difficulties.
	9	Now it's gone altogether. But you'll recall there
03:08:20	10	we go.
	11	You will recall on the July 14th, 2010, visit with
	12	Ms. Reed, the night before he unfortunately committed suicide,
	13	he told Ms. Reed that he was hopeful about a new medication he
	14	was taking, Paxil.
03:08:35	15	Now, remember all of the evidence you've heard in this
	16	case, ladies and gentlemen. When Mr. Dolin didn't like
	17	medication, he would call Dr. Sachman and change it. In fact,
	18	just a few days earlier remember, he was already taking the
	19	sertraline, and Mrs. Dolin said it just didn't make him feel
03:08:55	20	right. Nothing specific, he just didn't feel right taking the
	21	sertraline, he called Dr. Sachman and he changed to paroxetine.
	22	So, if think he wasn't feeling right or if he felt anything
	23	after taking the paroxetine, the evidence shows you that Mr.
	24	Dolin would have reached out, he would have told somebody,
03:09:15	25	because that is what the evidence shows happened not only weeks

1 before his death, but back in 2005 and 2006, when he had a 2 complaint with a medication, he raised it, but here, the night 3 before his death, he says he's hopeful. 4 So, let's look at the witnesses you heard from. Did 5 any witness come in here and tell you they saw evidence of 03:09:36 6 constant movement by Mr. Dolin? And the answer to that is "no." And I don't need to go through all of these names 7 8 because you heard from all of these witnesses, and none of them reported any constant movement on Mr. Dolin's behalf. 9 So what is the evidence of akathisia? 10 Outward 03:09:52 11 akathisia in this case. The evidence from Mrs. Dolin comes from, if you remember the testimony, there's an allegation that 12 13 he started taking Paxil on Saturday, July 10th. There were no 14 signs of agitation or constant movement on that day. 15 On Sunday there were no signs of outer movement or 03:10:11 16 constant movement on Mr. Dolin's part. 17 On Monday, July 12th, Mrs. Dolin noticed that Mr. 18 Dolin, when he got home from work, he got some phone calls and 19 he was pacing, and that was unusual behavior for him. Well, 20 surely the evidence you remember being that on July 12th is the 03:10:32 21 day that Standard Parking, that whole client thing that you 22 probably heard over and over again, you know the facts by 23 heart, but that Standard Parking called, they e-mailed Mr. 24 Dolin, and they had a problem because Reed Smith had sued 25 somebody, not an ethical conflict, but sued somebody that made 03:10:52

it a business conflict for Standard Parking, and they were
highly upset. And Mr. Dolin was worried about losing Standard
Parking. And you heard the testimony from those involved that
they were on the phone that evening, July 12th, that's when he
was pacing. He was upset about the phone call. But putting
aside the fact that even if he was pacing one night, that is
not constant movement required for akathisia.

8 The next day, Wednesday, there's no outward signs of 9 akathisia -- sorry, Tuesday. Tuesday, remember, is the night 10 that Dr. Sachman and Mrs. Dolin and Mr. Dolin went to a 11 memorial service and then went to dinner with friends, and they 12 spent over 2 hours together. And Dr. Sachman testified that he 13 was calmer, that Mr. Dolin was calmer than Dr. Sachman.

He also testified when he was on the stand that he knows what akathisia is and he would be able to recognize it, and he didn't see any akathisia, signs or symptoms in Mr. Dolin on Tuesday night when they had dinner together.

Now, Wednesday, Mrs. Dolin told you that Mr. Dolin
tapped his leg at dinner. So, there you have it, there was no
outward movement noticed by anybody on Thursday, you have some
leg tapping on Wednesday, and you have the pacing on Monday
night.

Now, Mr. Rapaport when he was making his closing remarks, he said when the attorney gets up here, well you can't ask him questions, but ask them the questions about why they

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1 said in opening statements that it was only Mrs. Dolin who 2 reported the outward signs of akathisia. And the answer is, 3 because that's the only witness that testified to any outward 4 signs of akathisia. 5 All of the witnesses in the blue you heard from, none 03:12:39 6 of them saw any constant movement, agitation, fidgeting, leg 7 tapping, or pacing. The only witness who saw that who testified was Mrs. Dolin. 8 Now, Dr. Glenmullen told you that Mr. Dolin showed 9 10 signs of pacing, agitation, and aggravated behavior all the way 03:13:01 11 back to 2000, and that medication was not required for him to be pacing and agitated back in 2000. That Mrs. Dolin had seen 12 it earlier in their marriage. 13 14 So, where did akathisia come from? Well, you'll 15 remember this testimony when Mrs. Dolin was on the stand, and I 03:13:24 16 asked her: 17 "Now, August 13, 2010, you recall is a date that 18 you decided to file the lawsuit, correct? Or to pursue legal action, correct?" 19 20 She responded: 03:13:40 21 "August 13th was the day I found some 22 information out. I don't recall that being the date." 23 24 I asked her: 25 "Okay. And the information you found out was a 03:13:48

		closing argument - by Henninger 4399
	1	friend of yours, Joanne, is it Moffett Silver?"
	2	Mrs. Dolin said:
	3	"Yes."
	4	" called you and said that she had talked to
03:14:01	5	the law firm of Baum Hedlund and wanted you to
	6	Google Paxil and akathisia?"
	7	And Mrs. Dolin responded:
	8	"Yes, Paxil, akathisia, and suicide."
	9	And I asked her:
03:14:14	10	" and you did that Google search, correct?"
	11	She said:
	12	"Yes."
	13	And I said:
	14	" at that point is when you decided to
03:14:22	15	pursue the lawsuit?"
	16	She said:
	17	" to start to think about it."
	18	That's where akathisia came from, ladies and
	19	gentlemen.
03:14:29	20	And what happened after that Google search? Well,
	21	Mrs. Dolin, later on, a couple of weeks later, she e-mailed Dr.
	22	Salstrom and she requested Dr. Salstrom not only provide her
	23	medical records but do a summary of her medical records. Those
	24	are in evidence. You've seen them a thousand times throughout
03:14:47	25	the course of this trial. Is there any evidence of akathisia

1 in those records? No.

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Then she e-mailed Terry Schwartz, remember the
business associate who had lunch with him just prior to him
leaving for the train station, and did he report any signs of
akathisia? No.

6 The same with the letter to Sydney Reed. She wrote
7 Sidney Reed, a friend and co-therapist of hers, and she
8 requested not only the records but a summary of the records.
9 And those didn't provide any evidence of akathisia, ladies and
10 gentlemen.

A finally she e-mailed doctor -- I mean, Mr. Pecoraro. You recall he was the witness who was down at the tracks that day. And you saw his testimony, but before he ever testified, before the lawyers ever asked him a single question he sent this e-mail to Mrs. Dolin on October 18, 2010, saying he noticed:

17 "... an individual pacing and agitated on the 18 O'Hare side of the Washington Blue Line stop 19 while I was waiting for my train to Forest Park. 20 I assumed he had an important appointment or 21 plans from the way he was looking down the 22 tracks and pacing about. This behavior is 23 routinely seen of individuals waiting on public 24 transportation, which is why I dismissed his 25 agitated behavior and continued waiting for my

		closing argument - by Henninger 4401
	1	train."
	2	Before any lawyers asked him any questions, that is
	3	what he told Mrs. Dolin.
	4	The plaintiffs always refer to this polar bear
03:16:13	5	reference, but you also recall in the deposition you watched
	6	his deposition, it was one of those videotaped depressions, it
	7	said the question was:
	8	"Would it be fair to say that his behavior was
	9	unusual?"
03:16:23	10	And he said:
	11	"No, that would not be fair to say."
	12	In fact, you heard from Dr. Rothschild that now in
	13	certain cities in the United States and Canada, they've
	14	installed cameras and they've trained people to look for people
03:16:39	15	pacing back and forth because it's a sign or indication that
	16	suicidal behavior may be taking place. So, that pacing before
	17	his suicide is not unusual, ladies and gentlemen.
	18	Now, I want to talk about what I heard a little bit
	19	when Mr. Rapaport was talking about Mr. Dolin briefly this
03:16:59	20	morning, he said something about he was distracted, that Mr.
	21	LoVallo said that he couldn't concentrate, and he had calls
	22	with his children where his children said he just sounded
	23	distracted and didn't sound like himself.
	24	Well, Dr. Salstrom explains this to you, because she
03:17:20	25	said that on June 29, 2010, when she first met him, that Mr.

Dolin conveyed to her that when he felt anxious, he would get
 distracted. This is before he was on any medication, ladies
 and gentlemen. Anxiety and depression cause distraction, and
 that's what he told Dr. Salstrom before he ever took a single
 paroxetine pill.

Now, 90 percent of this long board that Mr. Rapaport
didn't even have time to talk about related to the actions,
this alleged nosedive that Mr. Dolin took. 90 percent of those
have nothing to do with outward signs of agitation, none of
them.

And again, why is that important? Because plaintiff's theory depends on them showing that Mr. Dolin had akathisia. Dr. Healy said there's three ways paroxetine induces suicide. We talked about how emotional blunting is out and psychotic decompensation, so what's left? Akathisia. As we know, that's out too.

17 So, I want to talk a little bit about these burdens of 18 proof that Mr. Rapaport talked about when he showed the Scales 19 of Justice this morning and talked about how you have to tilt 20 them one way or another.

And if you look at the Scales of Justice, with the evidence lined up as to who saw any outward signs of akathisia, ladies and gentlemen, you will see that the scales are tipped in Glaxo 's favor.

But you know what, we do not have the burden of proof,

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ladies and gentlemen. GlaxoSmithKline does not have to prove
 to you that he didn't have akathisia. In fact, plaintiff has
 to prove that he did and they failed to do so. So plaintiff's
 claim that paroxetine caused Mr. Dolin's suicide fails.

5 So, what did the evidence tell you about Mr. Dolin? 6 Well, you've heard a ton of evidence about Mr. Dolin, about his 7 work, about his long history of anxiety and depression, and I'm 8 going to try to briefly remind you and move through this as 9 best as I can. I'll try not to talk too fast for the court 10 reporter's sake.

But you recall the timelines. And I'm just going to walk through these with you because this first timeline talked about how Mr. Dolin had a long history of work-related anxiety. The first time he started seeing any kind of mental health therapist is 1989. He's seeing a psychiatrist, Dr. Roth.

As everybody knows, we don't know a lot about what he saw or what he saw him for, but we know that there was an anxiety diagnosis at that time.

19 Interestingly enough, that also coincides with the
20 time that Mr. Dolin left the firm he was with and joined
21 Sachnoff & Weaver.

He stops his treatment with Dr. Roth, but Dr. Sachman prescribes him paroxetine for the first time. He filled 13 prescriptions of paroxetine or 390 pills from 2005 to 2006, and during that time he has no complaints of problems with

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1 paroxetine that he reports to Dr. Sachman.

2 Now, in 2006, the merger with Reed Smith, you heard so 3 much about was announced. And that's when Dr. -- I mean, when 4 Mr. Dolin starts going to see Ms. Reed. And he see Ms. Reed 5 starting in February of 2007. And he talks with her about 6 problems he's having. Problems related to his family doesn't 7 give him confidence, that he never had strong mentors who would 8 help him practice at a sophisticated level, that he couldn't 9 sleep, he was having a tough time holding it together, he was 10 anxious, fear plus escape. Those were the fears he was having in 2007 during this merger. 11

Now, ladies and gentlemen, you've seen all of these records, and I'm not going to go through them one by one, but you remember how he said that he felt frozen in his professional life, and he was worried about this merger. And these were Mr. Dolin's fears. It's not for us to second guess and say, you know what, he shouldn't have had these fears. That's not our job. These were his fears.

So that the fears continued and he gets prescribed another medication by Dr. Sachman, and this is when he starts taking sertraline. And he takes the sertraline, which was generic Zoloft, for a number of times here. Let me fill in the timeline a little bit so we don't have to walk through it too much, but Mr. Dolin took over 1,000 pills of sertraline with absolutely zero side effects reported.

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where Mr. Dolin indicates that he's having suicidal thoughts.

practice group is suffering, it's under budget. But he has

What's going on at work is also interesting, because his

December 1st, 2007, is the first record that we have

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these suicidal thoughts.

And you remember Dr. Glenmullen came in here and said, 6 7 well, he had those suicidal thoughts because of sertraline. 8 And I don't want to go down this rabbit trail very far, but just remember this, Dr. Glenmullen tried to claim is when his 9 10 sertraline was increased from 50 milligrams up to 100 11 milligrams, remember that testimony, but there's several 12 problems with it, because first and foremost, that dosage 13 increase occurred more than 6 weeks earlier.

So, that kind of goes against the testimony that Dr. Glenmullen gave that just one pill of paroxetine could send Mr. Dolin to suicidal behavior, but yet it takes 6 weeks for him to express that to his therapist in 2007. Which is it, 6 weeks or one pill? That's Dr. Glenmullen speaking out of both sides of his mouth, ladies and gentlemen.

Second, remember that Ms. Reed specifically talked about suicidal thoughts in December 2007, and she said that she explored that thoroughly and found it to be work-related. She talked with him about it, and she testified here in court via video, and told you about it. That's another example of Dr. Glenmullen differing from the facts in the case.

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1 So, I want to continue walking through the timeline 2 and I'm going to go a little bit further so we can get to 2009 3 and 2010, because you remember, you've heard the testimony, 4 several times of everything that started happening in Mr. 5 6 7 for everybody. 8 9 10 11

Dolin's world in 2009 and specifically 2010. The economy was terrible for lawyers. It was terrible And the corporate and securities practice group in which he was member was it hit especially hard. You recall the testimony about him being under budget. You recall all of the negative reviews that he got from his coworkers. And yes, you remember when Dr. Rothschild was talking about these 12 negative reviews he had with his coworkers, Mr. Rapaport said, 13 well, you didn't point out the positive ones. And that's true, 14 but Dr. Rothschild also said if you look at the earlier reviews 15 from 2007 and 2008, there was never a negative comment.

16 So this is the first time that Mr. Dolin's fears --17 remember, his fears and anxieties from 2007, they started to 18 resurface in 2009 and 2010, but the difference was, ladies and 19 gentlemen, was that at least to Mr. Dolin, his fears started to 20 become a reality. There were some evidence that he was getting 21 that fed those anxieties and fears.

22 And again, you've seen these records, ladies and 23 gentlemen, so I want to just briefly look at them. Remember. 24 he was dropped a tier in his compensation. And it was a big 25 shock, a seismic shock to him. And he appealed that, and the

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appeal was denied. And his salary was going down. And they
 appointed a new, younger co-chair of the practice group. And
 despite what he told all his friends and family, that wasn't
 his decision at all. It was Mr. Iino's decision, and you heard
 that.

And you also heard Dr. Glenmullen, when he was on the stand said that, you know what, this anxiety that we've talked about in 2010, that was nothing compared to 2007. That anxiety was way, way worse. Well, Mrs. Dolin testified that the anxiety he experienced in June 2010 was the same as 2007.

Now, Ms. Reed talks about how Mr. Dolin called her on
June 3rd, 2010, was he was highly anxious and he admitted that
the old fear loop, all of those fears from 2007 had been
triggered. And now not only have they been triggered, but they
were fed with some real-life evidence.

And again, all of these records you've seen, but I want to focus on the ones later on here, because what they show is that Mr. Dolin's fears were becoming reality, at least to him.

And remember, ladies and gentlemen, even Dr. Healy told you that it's not what the outside world believes, it's what Mr. Dolin perceived. In other words, because he told people that he didn't want to be a bag lady or that he was afraid of being fired, well we all heard that that probably wasn't anywhere near reality, but he thought it was. And it's

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not what the outside world believes, but what Mr. Dolin believes that is important. Dr. Healy told you that and Dr. Rothschild told you that.

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And Ms. Reed, she's the one who spent the most time with him in therapy that we have records and testimony from, and she described Mr. Dolin's highest stress periods as being the perfect storm between work, family, and Wendy's family, those were the major stressors, the perfect storm.

So, let's look at what was happening in 2010. 9 Again, 10 you see all of this evidence, ladies and gentlemen. And I 11 don't have to go through it all, but this is the perfect storm 12 this was occurring to Mr. Dolin in his world in 2010. And 13 these are found in the records from Dr. Salstrom, as well as 14 Ms. Reed. It's all in evidence if you ask for it. You can see 15 it yourself. He had thoughts of being a bad lawyer, he had 16 anxiety at work, he thought he was going to get fired, and he 17 was even considering, the age of 57, as to whether or not he 18 wanted to change his employment and go to a different law firm.

So, I want to remind you of the events of July 15th, because this shows his actions that day. And as you heard from Dr. Rothschild, people generally go about their business as usual on the day that they take unfortunate decisions, and this is what Mr. Dolin's day looked like. And what we do know is that he had a lunch date with Terry Schwartz. They were business associates. And they spent over an hour together.

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1 And Mr. Schwartz didn't notice anything unusual about him.

But he goes back to his office. And he goes back to his office and what does he get? What is waiting for him on his computer? It's an e-mail from Kevin Miniat who is pretty upset about the deferred vote.

6 Then Mr. Dolin calls Mr. LoVallo and tries to talk 7 with him, but he's not in. He sends him an e-mail, he's not 8 responding. Mr. Dolin leaves his office, and, unfortunately, 9 we know the rest of the story.

10 Plaintiff brought witnesses such as Mr. LoVallo and 11 others to tell you that there's no way or no evidence that Mr. 12 Dolin would've been fired, or that he would've lost Standard 13 Parking as a client, or that the Miniat thing was a very big 14 deal, but remember, it's what Mr. Dolin believed. And we know 15 what he believed because he told his wife. He told his wife 16 that he was very, very, very anxious about the meeting with the 17 Miniat family that Friday, and he also told his wife that he 18 was concerned that he would lose Standard Parking as a client. 19 That's what he believed and that's what's important.

Again, just showing that the fear loop he had in 2007 was coming true, at least in his mind, in 2010. Remember, he didn't feel qualified to work at Reed Smith, and then in 2010 somebody sends a very negative evaluation of him that talks about him being a "middle market lawyer from a middle market firm, enough said," these are more examples of how his fears

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		closing argument - by Henninger 4410
	1	were becoming realized.
	2	And Ms. Reed talked to you, she testified by video
	3	deposition, and the question was asked:
	4	"Do you agree that Stewart Dolin's anxiety and
03:31:01	5	life stressors, which are unconnected to any
	6	medication that he may have been taking, placed
	7	him at an increased risk for silicide thoughts
	8	and brevior?"
	9	Her answer was:
03:31:12	10	"Yes.
	11	She was the therapist that spent the most time with
	12	Mr. Dolin. Not a paid expert, his therapist.
	13	And the long chart that Mr. Rapaport talked about that
	14	has all of this information, and the argument is that it wasn't
03:31:34	15	until he took paroxetine that Mr. Dolin started exhibiting
	16	anxious and unusual behavior, I want you to remember that
	17	medication wasn't required for any of these entries:
	18	On June 3rd, Stu was highly anxious, much anxiety,
	19	confused about his feelings regarding his job, leaving or
03:31:50	20	staying.
	21	June 29th, many stressors at work, anxiety at work.
	22	I'm going to make a mistake and something bad could happen,
	23	stick in worry.
	24	June 30, still no medication, very anxious.
03:32:03	25	July 6th, no medication, client dysphoric, many

1 worries expressed, I'm a bad lawyer, I'm incompetent.

2 These are the things he was saying before he took a3 single paroxetine pill.

4 Now, I'm only going to briefly talk about Mr. Dolin's 5 uncoordinated character. You heard about it in opening 6 statement. And he was being seen by Dr. Sachman and two mental 7 health therapists, but none of them knew that they were seeing 8 the other ones, and none of them shared information. And, in 9 fact, the two therapists testified that their therapy was 10 competing. And Dr. Salstrom said, you know what, if he didn't 11 stop seeing Ms. Reed I was not going to see him. And Ms. Reed 12 said, you know what, I don't really like the kind of therapy 13 that Dr. Salstrom does, they don't mix with mine.

So, the therapy is complete -- the therapy is -- I can't remember the word now. The therapy is competed. But Dr. Glenmullen came in with an answer for that, because he's a highly paid expert, he's a professional expert, so what did he say? He said, oh, Dr. Salstrom hadn't started her treatment with Mr. Dolin yet.

Well, then again, let's look at the facts, let's look
at the testimony, and let's look at what Dr. Salstrom said
because she said that she was initiating therapy. Dr.
Glenmullen, the facts.

24 So, how do we know that the uncoordinated care would 25 have made a difference? Because Dr. Sachman, his dear friend,

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said that had he known about the suicidal thoughts that are expressed to Ms. Reed or Dr. Salstrom, he would've taken his good friend to a clinic, to a hospital to get help. He would've intervened.

5 Now, I want to briefly talk about inconsistent or 03:33:49 6 missing evidence, and the first is, how many paroxetine pills 7 did Mr. Dolin take? And there's a question as to whether it's 8 6 or 4. The only person who knows of the count is Dr. Sachman. And also, when did he take it? Dr. Rothschild got up here and 9 10 said he couldn't be precise, but some time he one pill, some 11 time within the last 4 or 5 days, and not a single question was 12 asked to challenge Dr. Rothschild's opinion on that. So we 13 don't know when he took it or how many he took. And we'll 14 never know. Why? Because the pills are no longer with us. 15 Mrs. Dolin threw them out.

> 16 You also recall the worksheet she received in Mr. 17 Dolin's briefcase when Reed Smith sent it to her home. She 18 said it had some pens and nothing else important in it. But 19 when I asked her about the worksheet, she said, yes, there was 20 a worksheet, and she called Dr. Salstrom about it. And this is 21 very important, because she asked Dr. Salstrom if she had a 22 copy of the worksheet because she thought that it may have been 23 written in his office before killing himself. It was a 24 worksheet entitled "values and goals."

> > And after she talked to Dr. Salstrom about it. and Dr.

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1 Salstrom said she didn't have a copy, Mrs. Dolin threw it away. 2 Now, Mr. Rapaport then got up on redirect examination 3 and said, "hey, have you seen this questionnaire?" "Is that 4 the same thing you found in Mr. Dolin's briefcase?" And Mrs. 5 Dolin said, "yes." 03:35:20 Well, ladies and gentlemen, look at the questionnaire. 6 7 You've seen this questionnaire. It's in evidence. Nowhere is there any discussion about "I don't want to," or any discussion 8 of values and goals. That's another piece of evidence that's 9 10 missing in this case. 03:35:38 11 Now, I want to make something very clear to you before 12 I move to the last topic, is that plaintiff's claim is that 13 paroxetine caused Mr. Dolin's death. GSK has no burden 14 whatsoever. However, GSK does not submit that there's any 15 reason. We do not have to prove why Mr. Dolin committed 03:36:00 16 suicide. And because plaintiff --17 THE COURT: Okay, wind it up as soon as you can. 18 MS. HENNINGER: And plaintiff didn't meet her burden 19 of proof, you must find against Mr. and Mrs. Dolin, against the 20 plaintiff. 03:36:15 Now, I want to just briefly remind you of --21 22 If I may, Your Honor? 23 THE COURT: Go ahead. 24 MS. HENNINGER: The damages, and you've heard a claim

03:36:23 25 for damages. It's the plaintiff's burden of proof to prove

closing argument in rebuttal - by Rapoport

4414

damages. And I want to remind you of the fact that Mr. Dolin's
 compensation was not level, it was not going up, but, in fact,
 the testimony and the evidence is that it was going down. And
 this chart shows it was going down.

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5 There's no evidence, although plaintiffs will show it 6 to you, they're going to say that you can average his 7 compensation at \$1.2 million. There's no evidence of that, 8 ladies and gentlemen, because, look, his last compensation was 855- was his budgeted compensation. There's no evidence that 9 10 he was going to work until the age of 70. In fact, Mrs. Dolin 11 said that they had talked about 65 to 67, and there's no 12 evidence he would've remained at Reed Smith.

Now, I want to end by saying it's plaintiff's burden of proof not only to prove all of the elements in her case, but also to prove damages. And not one witness came in here and told you what Mr. Dolin would be expected to earn in the future.

Finally, ladies and gentlemen, before you were seated as a jury you agreed not to let sympathy enter into your decision, and the Court will instruct you on that tomorrow. For these reasons, ladies and gentlemen, I want to thank you and I want to urge you that the evidence suggests that you find against the plaintiff. Thank you.

24THE COURT: All right. Thank you, Ms. Henninger.525All right. Mr. Rapaport, you may close.

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		closing argument in rebuttal - by Rapoport 4415
	1	MR. RAPOPORT: Okay. Great, Your Honor. Before we
	2	start that, I just need to set up the room. It'll only take
	3	about two minutes or so.
	4	(Brief pause)
03:38:23	5	CLOSING ARGUMENT IN REBUTTAL
	6	MR. RAPOPORT: All righty, we're down to the last
	7	step. Modern technology did let me take some notes while I was
	8	sitting there, so I have a few slides, a number of topics to
	9	cover, 22 minutes or so to do it, and I promise to be on time,
03:39:58	10	because if I wanted more time I'm not getting it anyway, right?
	11	With due respect.
	12	So, here we go. There's some problems with the
	13	defendant's arguments. Many of them, actually, I'll talk a
	14	little bit off the boards for a minute.
03:40:16	15	You know, fundamentally, we have people that hid data
	16	to the great harm of many, including this family. And they
	17	come into court and they pick at the deceased, they pick at the
	18	deceased's wife, and they pick at the deceased's doctor. And
	19	I'm going to show you in these 20 or so minutes that I have
03:40:40	20	left what the problems are at almost every level of that
	21	defense argument.
	22	So, first of all, there's no match between what the
	23	defense says and the questions that are on the verdict form and
	24	that are in the instructions that you're going to see.
03:40:57	25	So, these are our actual allegations. The first one

closing argument in rebuttal - by Rapoport

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is, "GSK provided an inaccurate warning label for paroxetine
 that hid the risk of paroxetine-induced suicidal behavior for
 people over 24 years of age," and also that it contained a
 misleading statement, that's number one and number two.

5 So, when they put up, we have to prove this, we have 6 to prove that, and we have to prove the other thing, there's a 7 total disconnect, actually. So, when you actually sit down to 8 do your deliberation, please follow the issues that the judge 9 gives you, because they are not the same as the issues that 10 defense provides. So that's problem number one.

11 Problem number two, GSK can't defend themselves on the 12 strengths of the other drugs in the SSRI class because there 13 were known suicide behavior risks that were worse for Paxil 14 than the remaining class members; however, if they could do 15 that defense, there are published articles that completely refute them. And I say Juurlink is your link, and I'm going to 16 17 show you what that means in a minute, and also Fergusson. But 18 I want to just go over the last bullet point here, then I'm 19 going to show you a bunch of slides that prove my point.

GSK claims there are no published studies linking Paxil to over 24 adult suicidal behavior. This is false as I will show you in the slides that follow, Juurlink and Fergusson, the studies by Aursnes and Barbui, because how they can step up here and tell you, as if it were true, that there are no published studies supporting the link between paroxetine

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1 and suicidal behavior is beyond me.

2 And I'm sure that you may all remember that these 3 studies were a discussion point when Mr. Wisner was 4 cross-examining one of the defense experts, and he put up the 5 names of the studies and pointed out how the studies that they 6 rely on all had big Pharma people that were running the 7 studies, and the studies that we were relying upon were 8 independent. So I'm just going to go over some of this in a 9 little more detail for you.

10 So, here is the Juurlink article. What is this? It's 11 probably the most important research in the area that's been 12 done. They have socialized medicine up in Ontario. They took the entire province of Ontario. They studied from 1992 to 13 14 2000, all of the deaths of people. Arbitrarily, they started 15 them at 66, because they wanted to look at older people. And they had perfect data because of socialized medicine about what 16 17 meds people were on. And they went through all of these 18 people, 1.2 million residents, and they looked at all deaths. Then they found a lot of suicides, and they studied those 19 20 suicides. And they studied the suicides in order to determine 21 just what it said here, about odds ratios for suicides on SSRIs 22 compared to other antidepressants.

And what did they come up with. Here's the results.
And I can't believe that they don't acknowledge this truth.
The results are that during the first month of therapy, that's

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1 just like the therapy that Mr. Dolin was on, these 2 antidepressants, the entire class, were associated with a 3 nearly five-fold higher risk of completed suicide than other 4 They show you that it's actually a 4.8 odds antidepressants. 5 ratio, 95 percent confidence ratio, statistically significant, 6 and that this was independent of a recent diagnosis of 7 depression, like Mr. Dolin had, and the receipt of psychiatric 8 care, like Mr. Dolin had, and suicides of a violent nature were 9 distinctly more common during SSRI therapy.

10 They showed you a quote out of this article that is 11 This article completely supports this case. total nonsense. 12 It shows the pattern of exactly what happened to Mr. Dolin. 13 What the people at GSK knew what was happening to some people, 14 a small portion of the total population is vulnerable to these 15 True with the whole class, but Paxil is the worst drugs. 16 member of the class. It's not Dr. Healy's problem that Dr. 17 Juurlink didn't have the drug-by-drug data. When they do 18 further work on this, they will do, and when they do get it 19 they're going to show that Paxil is the worse in the class and 20 that it's probably more of an eight-times risk than the five 21 that's the class average.

So there's one article. Here is the data, here are the odds. Here are the drawings that Dr. Healy showed you that brought out how it's in the first month of treatment, and it's a five-fold risk. You can see it right there n the drawing.

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	1	And then here you saw this drawing as well. Please don't
	2	forget these things. This is showing that the pattern of the
	3	SSRI induced suicide is violent, just like what happened to Mr.
	4	Dolin. And it comes on in the first month, just like what
03:46:05	5	happened to Mr. Dolin. That's what we have.
	6	All right. And then secondly, on the SSRI class,
	7	there's the famous Fergusson article that Dr. Healy was a
	8	co-publisher on which put out the odds ratios are increased
	9	across-the-board for the class.
03:46:22	10	So, I made the point here about the class, now let's
	11	get to their statement about no published articles that show
	12	the connection between their drug, paroxetine, and suicidal
	13	behavior. Well, here's one, August 22nd of 2005. This is our
	14	songs:
03:46:41	15	" the conclusion, patients and doctors should
	16	be warned that the increased risk of suicidal
	17	activity observed in children and adolescents
	18	taking certain antidepressants may also be
	19	present in adults."
03:46:54	20	And this entire article was about paroxetine, and you
	21	can see the title. And you can see, you know, over here they
	22	talk about metaanalysis, and they conclude the way they did,
	23	but this isn't the final word on this one. What's even more
	24	important is what they said in '06, which I want to come back,
03:47:13	25	because the folks across the table, or at least their client,

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pushed back against Dr. Aursnes and the others, and here is
what they had to say in November of '06, "following our
previous publication," and again, this is even more suicide
attempts in clinical trials with paroxetine randomized against
placebo. How they can't say there isn't something on the
topic, hard to follow, but here they say:

7 ".... we were in our previous publication with
8 preliminary data in a Bayesian approach, able to
9 raise a concern that suicide attempts might be
10 connected with the use of paroxetine."

11 This suspicion has no been confirmed. Look at this, 12 folks. I mean, we have them caught in a red-handed 13 misstatement to you. There's no published articles making the 14 connection? What are you talking about? On November 28th of 15 2006 this group of very prominent, independent doctors and 16 researchers concluded that there is suspicion that paroxetine 17 caused suicide attempts and suicides was now confirmed. And in 18 the body of this, they talk about how the folks here, GSK, you 19 know, pitched these people the same stuff that they're trying 20 to pitch you, and they took it apart.

Interestingly enough, GSK is now in the briefing
document, changed numbers, they talk about all sorts of things.
Look at this, this can be described as data drowning. That's
what these people do, they data drown. They hide signals, they
play games. This is a risk that they've known about for a

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	1	long, long time.
	2	Here's even more on that. There's also the Barbui
	3	article, which is showing increased risk for paroxetine over
	4	placebo concerning the suicides here. So, that's what we have,
03:49:06	5	experienced suicidal tendency, there's another increased odds
	6	ratio. They have odds ratios against odds ratios, that's what
	7	goes on.
	8	So here, what's the next thing we have to say?
	9	Problems with defendant's arguments, they talk about Dr.
03:49:24	10	Sachman, but you know what, they ignore some of the most
	11	important things that Dr. Sachman had to say. One example
	12	whoops.
	13	Let me get back to where I am here.
	14	(Brief pause).
03:49:37	15	MR. RAPAPORT: One example is his testimony:
	16	" I'd like to say that in midst of all of this
	17	attempted confusion of the real issue here"
	18	and this is Dr. Sachman after he had been
	19	cross-examined for an hour, or however long it
03:49:52	20	was:
	21	" in the midst of attempted confusion of the
	22	real issue here, if it was clear that this drug
	23	had a higher risk of causing suicide in the age
	24	group Stewart Dolin was in, I would have never
03:50:05	25	prescribed it."

closing a	rgument	in	rebuttal	-	by	Rapoport
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Okay, that's his testimony, and he gave it strongly
 because it's true. He had no appreciation. And he said other
 things that -- let me just pull up a few other things from Dr.
 Sachman.

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So, he's asked, and he gave you the testimony: "... first thing that's apparent from the label is the black box warning ..."

he testified. He testified that it talks about 8 9 increased risk compared to placebo for suicidal thinking and 10 behavior in children, adolescents, and young adults under 11 certain circumstances. He testified that he relied on that. Did he believe it to be truthful at the time? Yes, absolutely. 12 He told you what the consequences were when doctors don't get 13 14 the truth from drug companies the way he didn't get the truth 15 Now they want to turn this around to say he in this case. 16 would've prescribed this if it had a warning on it that said 17 suicidal behavior for people of any age? And why would he? He 18 had a whole panoply of other drugs that didn't have that problem. Why would he? Why would anybody give a drug that had 19 a suicide risk to somebody? So there's a part of what I wanted 20 21 to point out to you.

Now, part is the label itself. Here we have the falseand misleading thing:

"Short-term studies did not show an increase in the risk of suicidality with antidepressants

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compared to placebo in adults beyond age 24."

Well, you know what, folks, for Paxil they did, they 2 3 did. They did from day one, and they did throughout. There 4 was never a time when Paxil did not have an increased risk of 5 suicide for people of every age. There's been no -- how do we 6 call it, there's been -- there's been no biological explanation 7 for why this drug wouldn't affect people the same way of different ages. People are people. And whatever goes on with 8 some of the other SSRIs, this was one is the worse or second 9 10 worse of the group, and it's high time that their label told 11 the truth so that people will know.

12 And you know what, this is an industry that's changed 13 the world on us, folks. Some of us here are old enough to 14 remember when you wanted a medication like this, you had to see 15 a psychiatrist. The general practitioners' world has 16 completely changed during the life of Dr. Sachman, and now 17 people like Mr. Dolin, who, frankly, was not a severely 18 mentally ill person -- I mean, you don't -- you know, the 19 instructions tell you to keep your own common sense, and you should, because it's hard to find a nicer guy. And this isn't 20 21 a big lie on the outside. The truth is that people have a 22 right during their lives to see a counselor if they want to, a 23 social worker, or a psychologist, and not to tell everybody in 24 the world whatever they may be discussing. Everybody has 25 different reasons that they may think about such a thing.

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this case, because there was no warning that the drug caused

risk for people over 24. The label said the opposite, that's

the problem, if it wasn't we wouldn't be here.

So, anyway, keep in mind where the big falsehood is in

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5 There are problems with defendant's arguments about 6 Dr. Glenmullen. He showed you the symptom complex that he 7 relies upon. He included, but never limited it to akathisia. 8 He also showed you that akathisia does not depend on outward 9 manifestations, and you can see that right in the standard that 10 defines the diagnosis. So -- and I make the statement that 11 absence of constant movement by Mr. Dolin while he was on the 12 drug is no defense, it's a phony defense.

Here are the exhibits briefly that he showed. It's right out of the label. This is the symptom complex, and it's in total. And then he showed you which symptoms Mr. Dolin had in the last 6 days, and they were all summarized on that board.

And here is the definition that was given, which are
subjective complaints of restlessness, subjective complaints of
restlessness, then it says, "often" which you can read as often
but not always, "often accompanied by observed excessive
movements." So there were some excessive movements observed at
points, but let's remember that we heard clear scientific
evidence about how a drug like this can flip a switch.

And it does make you wonder, you know, Dr. Rothschild, who doesn't tell you everything that was found on Mr. Dolin and

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1 leaves out, for example, that he had his Metra ticket in his 2 I mean, what would somebody that was planning a pocket. 3 suicide have use of the train ticket that takes them home for? 4 Nobody knows what his intentions were when he set out for that 5 walk. I do know that he was a successful lawyer in Chicago, 03:55:04 that Wicker Park is one of the growing areas. I'm sure he had 6 7 plenty of clients that were building things there --8 MR. BAYMAN: Objection, Your Honor. That's not in 9 evidence. 10 MR. RAPOPORT: People live in Chicago, and we're 03:55:18 11 talking about common sense. 12 THE COURT: Proceed. 13 MR. RAPOPORT: So, anyway, the Blue line has a stop at 14 Division, it's walking distance to the Metra stop at Clybourn, 15 that you can take that to Glencoe, if you want. The point is, 03:55:32 I didn't know what Stewart Dolin was going to do. I wish he 16 17 were here to tell us --18 (Phone call interruption coming from the 19 government's audio system.) MR. RAPAPORT: -- but they certainly don't know, and 20 03:55:39 21 they just leave out all kinds of facts. You know, they don't 22 tell you about the prized watch he has in his pocket. They 23 completely overstate what his business life was. He had a few 24 problems, but, you know, his problems were the same kind of 25 thing that he's had for 30-plus years. You know, am I a 03:55:54

		closing argument in rebuttal - by Rapoport 4426
	1	shareholder, or whatever
	2	THE COURT: Just a minute. I hear somebody's cell
	3	phone?
	4	MR. RAPOPORT: I don't know what it says.
	5	THE COURT: If you would lift that phone up, Blanca,
	6	and shut it off.
	7	(Brief pause).
	8	THE COURT: Blanca, can you shut that off?
	9	I'm sorry, folks, I'm not good as a tech either.
03:57:15	10	(Audio interruption corrected.)
	11	MR. RAPOPORT: Talking about white noise, most of
	12	their argument was a bunch of white noise. What I think about
	13	what I think about this case is, "oh, what a tangled web we
	14	weave when first we practice to deceive." And you know what,
03:57:29	15	folks, we haven't deceived you about a single thing. We
	16	brought you the truth. We've been fighting hard on behalf of
	17	this client and on behalf of this cause, because we believe in
	18	it. And we brought you some people that I think you could see
	19	the difference between the people that we bring and the folks
03:57:43	20	that they did, at least I hope you see that.
	21	So, let's see what else we have here. Akathisia, you
	22	know, it doesn't cause suicide, or whatever. Here's testimony
	23	from Dr. Rothschild from the trial agreeing that akathisia is,
	24	in fact, associated with Paxil. And here's a quote from his
03:58:04	25	book, making clear that he has published that he also believes

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that akathisia is connected with suicide, you know, anxiety
 increases risk of suicide.

So, these people are sitting there going, you know, we haven't proved our case. Oh, yeah, we've shown you what the pattern is, and the pattern has affected plenty of people. We already talked about police report stuff. So, you know, I could zip through all of their experts, and, you know, sort of lay it out, but we all know, I haven't a lot of time.

But I got all of that (indicating), you can't read
fast enough, but if there were more time I probably wouldn't
take your valuable time because enough of that has been taken
away, but I'm showing you all the problems with all their
different experts.

And they all have something to say, but I'll tell you what they can't get past: They can't get past that we know the pattern, and this case fits that pattern like a glove.

Now, I want to move in for a final point or two by
hoisting this board up here. And while he's doing that I'm
going to explain a point of view law to you, okay, because they
love to blame anybody and everybody else.

But let me tell you something, that one cause business, when you read those instructions carefully, you will understand that -- okay, I'm going to start that again.

When you read those instructions carefully, you will understand that it not only is it not our burden to prove that

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1 it was the only cause or the last or nearest cause, other 2 causes can be in play here. I said to you right at the very 3 beginning that this may be a case about shared responsibility. 4 So you know what, how much actual fault does GSK have for us to 5 be entitled --03:59:51 6 MR. BAYMAN: Objection to this. 7 MR. RAPOPORT: -- to your verdict? 8 MR. BAYMAN: He's interjected the fault which is not 9 in this case. 10 THE COURT: Proceed. Proceed. 03:59:58 11 MR. RAPOPORT: So how much fault does GSK actually 12 need to have in this case. When you read those instructions 13 carefully, I think you will understand that it doesn't make any 14 difference, even though Marty Sachman didn't do anything wrong, 15 doesn't make any difference, you may think he did, you might 04:00:14 think the FDA did, they're talking about uncoordinated 16 17 communication with psychologists, or whatever; 1 percent fault 18 is all we have to prove here, folks. 19 The reality is, our legal standard is not that stuff. 20 Now you know what, we have a board here that backs up the 04:00:28 21 pattern that we've shown. It's about violent suicides. These 22 are just the ones in their clinical trials. Okay, you know 23 that there are at least 30 more because that's how many they've 24 hired Dr. Rothschild did, who always says couldn't be our drug 25 and picks at whatever weaknesses there were in the person who

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		closing argument in rebuttal - by Rapoport 4429
	1	went down.
	2	So, you know what, there's probably a hundred other
	3	things to say, but I'm only going to say one.
	4	But first I'm going to do this (indicating).
04:01:07	5	(Brief pause)
	6	MR. RAPOPORT: What happened to Stu Dolin could've
	7	happened to anyone. And, as a matter of fact, we haven't
	8	talked about the homicidal aspect of what they know these drugs
	9	do
04:01:22	10	MR. BAYMAN: Objection, Your Honor.
	11	MR. RAPOPORT: but what happened to Stu Dolin
	12	MR. BAYMAN: Homicidal?
	13	MR. RAPAPORT: I'm just finishing.
	14	THE COURT: Strike the word "homicidal."
04:01:29	15	MR. RAPOPORT: Okay. My final point, okay, is take
	16	back there with you your common sense, take back there an
	17	understanding that we're not seeking sympathy. Neither should
	18	you give this big pharmaceutical company that did what they did
	19	here any bit of sympathy. We'll rely on your common sense.
04:01:48	20	You've sat here and you've heard all of this. Truth is a
	21	little bit like the old milk bottle that only some of us in the
	22	room will remember. The milk bottle when it came in glass and
	23	was delivered that had the cream sort of rise to the top, okay.
	24	The truth sort of is like the cream that rises to the top, and
04:02:08	25	I believe that you will know what to do when the time comes.

closing argument in rebuttal - by Rapoport 4430 1 I thank you on behalf of the Dolin family, on behalf 2 of this legal team. Thank you. 3 THE COURT: All right. Thank you, Mr. Rapaport. 4 MR. RAPOPORT: And you know what, I forgot something. 5 It was important. I'm that way. 04:02:24 6 THE COURT: All right. Go ahead. 7 MR. RAPOPORT: I had an excellent idea handed to me by 8 one of my colleagues, which is show the jury the form and show 9 how to fill it out. 10 So, there's the form (indicating). Needless to say, 04:02:38 11 we want you to forget about all those red X's that my 12 colleagues on the other side of the room had --13 I don't think this is rebuttal. MR. BAYMAN: 14 THE COURT: Well, I don't know that it is, but go 15 ahead. 04:02:54 16 MR. RAPOPORT: Rebutting red X's. 17 And here is how you can fill out the numbers in the 18 space allotted (indicating). And then the signatures, of 19 course, you would have to do your own. 20 So I thank you, and wish you the best as you begin 04:03:06 21 your deliberations. Thank you. 22 THE COURT: All right. Thank you very much, counsel 23 for both sides. 24 And ladies and gentlemen, I have to stand up because 25 they've blocked me here. 04:03:20



	closing argument in rebuttal - by Rapoport 4432
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4	I CERTIFY THAT THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE
5	RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER
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7	/s/Blanca I. Lara April 18, 2017
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