Opening Statement - Mr. Rapoport (Resumed) (Change of reporters - Volume 1-C) (In open court outside the presence of the jury:) (Jury in at 3:01 p.m.) THE COURT: All right. Thank you very much, Ladies and Gentlemen. Please be seated. We'll resume. THE COURT: All right, sir. MR. RAPOPORT: Thank you, your Honor. OPENING STATEMENT (RESUMED) BY MR. RAPOPORT: MR. RAPOPORT: Welcome back. Okay. So what we've been talking about is the part of this -- really just to orient you, telling three stories -- of the story of what the evidence is going to show GSK's conduct was, which we talked about, the story of what was happening in

medicine and what's different about these drugs with general practitioners, which we talked briefly about. And for a while now, maybe in less interesting part, we've been going through a lot of different office visits and medical records about mental health care.

So what I really want to do is zero in so we can get at the heart of this, and it is that when -- he went on the drug on July the 10th of 2015.

We're not quite there yet, but I wanted to just have you understand that that's where we're aiming, so when we're here at June 30th, we are -- he's off all medications now. And you can see that right here. This is conceptually just around two weeks before his death, okay? So off all medications now.

And we know he was on Zoloft briefly, it didn't work out. On June 27th, he was given a prescription of Paroxetine that brings us here today, but he didn't start taking it yet, and here's some of the proof of that. He's off all medications now.

He explained to Sydney Reed that he was seeing this other therapist who uses behavioral methods, and that the other therapist asked that she be the sole therapist, basically, that she didn't want to have two therapies going on at the same time.

Now, Sydney Reed, you saw all of these many office notes, and, in summary, the office notes are showing talk

Opening Statement - Mr. Rapoport (Resumed)

y. That's what we're dealing with. She was a social

worker giving talk therapy to a man who had the various things that we looked at already.

So the therapist had helped him, Sydney Reed wrote that day, and that he was conflicted about giving up working together with Sydney Reed, that he was very anxious, but she suggested that he keep up exercise and come back if he wants.

So this is a transition of sorts, but you will see that he sees her again, so we'll come -- you'll see all of that as it happens.

So let me get back to where we were here.

In session number two -- there will be a total of three sessions with Dr. Salstrom.

In session number two, which was on July 6th of 2010, she wrote that he was expressing worries but motivated, that -- she's got some fancy language in there that she explains in her deposition about anxiety, depression, sharing elements of experiential, whatever. I'm not going to dig into that. I want to zero in on the suicide stuff.

So there's no mention here of any suicidal thoughts, just like there was no mention of any suicidal thoughts in her notes before this.

And we go on from here. Dr. Sachman actually didn't see Stewart Dolin in the office on July 10th, but this is a time when he had documented the switch to Paxil that he had

Opening Statement - Mr. Rapoport (Resumed) 1 actually written a prescription for somewhat before this. So 2 Dr. Sachman --3 MR. BAYMAN: Your Honor, I just ask that he use the word "Paroxetine," the drug that he was taking, rather than 4 "Paxil." He continues to use "Paxil." 5 6 THE COURT: Keep it clear and proceed. 7 Okay. And, your Honor, did you want me MR. RAPOPORT: 8 to avoid "Paxil"? I'm just not sure. To me, it's clearer to 9 say "Paxil," but --10 THE COURT: Well, it depends on the context. Proceed. 11 MR. RAPOPORT: Thank you. 12 So, anyway, I'm reading a direct quote here from 13 Dr. Sachman's office, where Dr. Sachman wrote about Paxil, so 14 that's -- that's where my comment came from. 15 So -- so you folks understand, Dr. Sachman will 16 explain that he did see Stewart in the last week of his life, 17 in fact, just a few days before. He didn't notice anything 18 unusual. Other people will be giving testimony along those 19 lines. But he did not see Mr. Dolin in his office on 20 July 10th. 21 So the -- July 10th was a Saturday. And here we are 22 showing you that this is the day that Mr. Dolin started taking 23 Paxil. That's what the evidence will show, and I'm going to 24 show you the evidence now that shows it, which is in the third

session, actually -- I said I'm going to show it to you, but

apparently we didn't clip that part. In the third session on July 12th, Dr. Salstrom mentions that he started on Paxil the Saturday -- Saturday. That's kind of how we know, so Saturday was July 10th before this. And here you have a significant change two days into the med., so -- that's what the evidence will show.

First of all, she writes he is much worse. Dysphoric, which I think is another word for depression. This is a quote: Client easily gets distracted by worry thoughts in session.

And then she wrote -- or said there were passive suicidal thoughts without a plan, that he's stuck in worry or rumination.

So this is the second time in his life when somebody wrote down there were passive suicidal thoughts. The first time was shortly after the dose of Zoloft was doubled, and the second time was when he was two days into taking the Paroxetine that Dr. Sachman had prescribed. Dr. Salstrom made the decision that a good follow-up would be talking by telephone on Friday of the same week.

I hit the wrong button.

Carrying this forward now, we are July 14th. This is one day before the tragic events. And here you have the notation from Sydney Reed's records about what happened that day, and I'm going to take us through this slowly.

So he called in the morning, that he wanted to come

in. He said he might be having a nervous breakdown. That evening he was highly anxious and more depressed. He was facing a difficult meeting at work. Talking it through, he said he could handle it. Walked through family issues, separating feelings from facts. He decided to increase his exercise schedule. There were additional stress management exercises given. He denied any thoughts of suicide when he was asked. He was hopeful about a new medicine he had started, which she wrote as Paxil. He also wanted to discontinue with the behavior therapist and return for his weekly sessions, and he agreed to call her on -- Thursday night is -- the very next night, this is a Wednesday night, so call the next night.

Now, the evidence is going to show that Sydney Reed woke up the next day and was -- didn't wait for the call, that she actually called Mr. Dolin at around 10:30 in the morning, and she suggested to him that he call his doctor for a fast-acting anxiety drug to help him with his anxiety, and that's where the mental health records end, and that's also where the medical records end.

So you will hear the testimony of Sydney Reed. You'll hear the testimony of Dr. Salstrom. Neither of them thought that Mr. Dolin was suicidal. The night before his suicide, he expressly was not thinking about suicide and told her as much.

She was concerned about his anxiety because both of the two mental health professionals that he saw after he

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started taking the Paroxetine on July 10th -- that would be Dr. Salstrom on July 12th and Sydney Reed on July 14th -- both of them noted a substantial change in his condition that occurred shortly after he started taking the Paroxetine. this was an unusual thing. He and Sydney Reed had what is now a several-year relationship, even though he wasn't seeing her all the time, but he, for periods, he would see her quite regularly, as you've just seen, over the four years, and they knew one another quite well. Never before July 14th had she woken up the next day after a session and wanted to call him and say maybe get a fast-acting anxiety drug. As a matter of fact, never before had he called her to set up an appointment that wasn't set up in the fashion that he did that day, and never before had he said I think I'm having a nervous breakdown. There were things that were different about Mr. Dolin after he started taking the Paroxetine.

Now, does that mean that everybody who he came in contact with noticed things that were different? No.

You will hear people, for example, Mr. Terry Schwartz, who is an accountant and an acquaintance and a business colleague, had lunch with Mr. Dolin the very day that he died. And his day began with exercising at home. He then -- he had a normal morning and he had a normal lunch where his co-workers didn't notice anything particularly unusual. And what -- who was the last person that actually saw Mr. Dolin, well, we don't

know because it's down in the Blue Line subway station. But what we do know is that there was one person, a nurse, Mr. Pecoraro, who noticed Mr. Dolin and who also stuck around and gave his statement, and so you will hear from him, even though he also lives out of state -- so you'll hear from him as well by way of video evidence deposition -- but Mr. Pecoraro saw Mr. Dolin in the Blue Line station here at Washington, and he was in between a couple of posts in the station, and I can't repeat exactly what this was like, but he described it as pacing, pacing, like almost a caged animal, like, pacing. This is the last thing that was seen. And the subway train came speeding into the station, and Mr. Dolin leaped in front of it.

Now, we don't have a full account of all of the time from the time that the lunch ended and the time -- at 1:15 -- 1:50, I misspoke, 1:50 p.m. on Thursday, July 15th of 2010, when, roughly, Mr. Dolin's life ended. It ended quite violently, and you will hear some evidence about that, but we're not going to dwell upon the precise details of all he went through associated with the collision, with the train, and the contact with the electrical and other things that occurred.

So that is the three stories.

I want to -- I want to take a couple -- I better stay near this thing.

I want to take a couple of minutes and try to bring these together, and at the same time maybe we can -- does that

Opening Statement - Mr. Rapoport (Resumed) get rid of that? There we go. Okay.

So what do we know here?

The evidence will show in this case that it was known from the start of the clinical trials that people associated with Paroxetine were killing themselves usually in violent ways not too long after they started taking the Paroxetine.

This was a greatly increased risk over what was happening to people that were of the same cohort, but who were taking sugar pill placebo instead. This greatly enhanced risk was known to GSK, but GSK did not put it in the label, and they were not candid with the Food and Drug Administration at that time. We went many, many years with no suicide warning.

Now, let me explain what that means.

There are things in the label that talk about depression itself is associated with suicide and, you know, that people with depression, you've got to look at that, and there are various things at different points in time that are in the label; but that is not the same thing as the label saying that this drug is associated with drug-induced suicide, this drug causes drug-induced suicide. It doesn't cause it in everybody that takes it. That's why this is not a case about the drug never should have come to market. This is a case about how doctors needed to be informed, because, you see, it's a system of reliance, folks. The doctors rely on the pharmaceutical companies in order to honestly tell them about

Opening Statement - Mr. Rapoport (Resumed) 1 known risks. And we, the patients of doctors, rely on the 2 doctors and the pharmaceutical companies, because the entire 3 thing falls apart when there isn't candor because somebody 4 doesn't tell what they know about risks that are, in fact, 5 discovered. 6 And so this situation went from '89 until 2003 or so, 7 2004, when there was a big stink about the juvenile, finally 8 a -- some suicide warning went on, but the suicide warning that 9 went on went on for a whole class of drugs, and it talked about 10 for people 24 and younger. There was no suicide warning put on 11 Paxil for adults, even though GSK has known that there's 12 increased risk of suicidal behavior for adults, and the pattern 13 is apparent. It takes people who --14 MR. BAYMAN: Your Honor, I'm going to be object under 15 404. Propensity evidence now --16 THE COURT: Well --17 MR. BAYMAN: -- because something happened, it means 18 it happened in the future --19 THE COURT: I think you're verging on argument now, 20 sir. 21 MR. RAPOPORT: Okay. 22 THE COURT: Your function now is to tell the jury what 23 the evidence will be. You'll have an opportunity later in the

case to argue the evidence, but not now.

MR. RAPOPORT: Okay. I accept that.

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THE COURT: Just what you think the evidence is going to be.

MR. RAPOPORT: Will do.

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So the evidence in this case is going to show the story number one that I told you about known risk that was hidden, obscured, and not revealed. Known risk that should have ended up in the label is what the evidence is going to show.

The evidence is going to show that if the proper warning had been put in, Mr. Dolin would have never been given Paxil, and this suicide would not have occurred because the evidence is going to show that this normal family man, this excellent and hard-working lawyer, this person who was making a million dollars a year, this person who had a \$3 million net worth and no debt, this person who had nobody that was trying to kill him and who didn't have a bad childhood, this person who had anxiety and some depression, who is exactly who these drugs are supposed to help, prescribed by a general practice doctor because he had problems, but none of the professionals working with him thought he needed a psychiatrist. Instead, it was take a pill. But there was a dirty little secret about the That's what the evidence is going to show. dirty little secret about that pill killed a very good man. His family is going to be here seeking justice for his destroyed earning capacity --

Opening Statement - Mr. Rapoport (Resumed) MR. BAYMAN: Your Honor, we're now really on argument 1 2 here, seeking justice --3 THE COURT: You argue the case later, please. MR. RAPOPORT: The evidence will --4 5 MR. BAYMAN: Can I ask that the jury disregard that, 6 your Honor? 7 THE COURT: Yes. 8 MR. RAPOPORT: The evidence will show the things I 9 just mentioned about the goodness of this man and what his 10 issues were and what they weren't. 11 The evidence will show the earnings that I just 12 described. 13 The evidence will show his normal work life and life 14 expectancy. 15 The evidence will show that this man's death should 16 not have happened at that time. 17 The evidence will show that not only should he still 18 be with his family and fine, but that he should be working at 19 the Reed Smith law firm and he should be continuing to work for 20 as long as he wanted to work. 21 The evidence will show that this family has lost \$12 22 million in lifetime earning capacity, and that's before we 23 begin to talk about the fantastic man that this -- that this 24 wife and this -- and these children have lost.

His Honor will tell you the law later. I cannot argue

how the law applies to this case at this time. There will be another time for that. I've tried hard to only tell you what the evidence will show in this case.

And the bottom line is the evidence will show that that corporation is at fault for this death. And you watch -- if the evidence shows that anybody else also shares in fault, like Mr. Dolin or any -- Sydney Reed or anybody else, the evidence will show whatever you conclude it does, but Stewart Dolin paid with his life, and the question in this case --

MR. BAYMAN: Your Honor, this continues to be argument. This is like a closing argument.

THE COURT: All right, wind it up, sir.

MR. RAPOPORT: All right. I'm going to wind it up by saying this: Fault can be complete or shared, and we'll see what happens here.

Thank you.

THE COURT: All right. Thank you, sir.

All right, Counsel?

MR. BAYMAN: I think the court reporter has to switch the system over.

THE COURT: Are you ready?

MR. BAYMAN: Switching from their system to our system.

THE COURT: Oh, I see, okay.

OPENING STATEMENT BY MR. BAYMAN:

MR. BAYMAN: May it please the Court, Counsel, Ladies and Gentlemen of the jury.

I want to first start off by thanking you for your service as jurors. It's a very important duty in our society, and we appreciate your time and your attention over the next few weeks as we tell you about this case.

This case is about Stewart Dolin, Ladies and Gentlemen.

And I'm Andy Bayman. I'm pleased to represent GlaxoSmithKline and this company, along with my colleagues, Todd Davis, Ursula Henninger, and Alan Gilbert who you met this morning during jury selection.

You also met Mr. Andrew Boczkowski, who is with GlaxoSmithKline, or GSK, earlier this morning.

We're proud to represent the men and women of GlaxoSmithKline, a pharmaceutical company that makes medicines to treat serious medical conditions and diseases all over the world.

One of those medicines that GSK manufactures is a medicine called Paxil. It's a prescription medicine that has helped people cope with the debilitating effects of depression and anxiety from --

> MR. RAPOPORT: Objection, your Honor.

THE COURT: Proceed.

MR. BAYMAN: There's been some confusion because

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you've also heard the term "Paroxetine" today.

Paroxetine is the chemical name for the medicine that later became marketed by GSK and sold as Paxil, the brand name, so in some documents that you will see, you will see the name Paroxetine.

However, Paroxetine is also the name, as your Honor instructed you at the beginning, of a generic medication manufactured by another company. That's the medicine that Mr. Dolin took before his death. Mr. Dolin took Paroxetine, not Paxil.

We all have sympathy for the loss that the Dolin family has experienced. This case is a tragedy, but all suicides are tragedy.

MR. RAPOPORT: Objection, your Honor. Argument.

THE COURT: Proceed.

MR. BAYMAN: Ladies and Gentlemen, though, generic Paroxetine did not cause Mr. Dolin to take his own life.

We've got a lot of ground to cover in this case; but as you hear the evidence, I want to ask you to consider four questions.

Let's look at those questions.

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

The answer to that question, Ladies and Gentlemen, is Mr. Dolin's longstanding battle with anxiety and depression, which started long before he ever took Paroxetine, plus the

significant and increasing work stresses he was experiencing right before his death.

This case is what happened to Stewart Dolin in 2010, not about what went on in 1989 or 1991, before -- long before Mr. Dolin ever took Paroxetine.

Now, Mr. Rapoport said this part may be the less interesting part of the case, but actually I would submit to you, Ladies and Gentlemen, it's the most interesting part of the case, because it's about Stewart Dolin and what happened to Stewart Dolin.

Mr. Rapoport went on for 60 minutes talking to you about the history of the drug and interactions with the FDA before he ever told you about Stewart Dolin. I'm going to start with Stewart Dolin, and I'm going to tell you the rest of the story.

During the course of this trial, you're going to hear a lot of personal information about Mr. Dolin, including what he was telling his therapists in private sessions.

Now, normally, medical records are private; but because of this lawsuit, we must look at those records to help answer the question of why did Mr. Dolin take his own life.

And you're going to see those therapists' records, written in the therapists' own handwriting, with their own shorthand, and I'm going to put some of those on the screen in just a few minutes.

The therapy records show that Mr. Dolin had a 20-year battle with mental illness which peaked when he faced difficult situations or uncertainties at work.

The evidence will show in the weeks and months before his death, Mr. Dolin started to face more and more problems at work.

And in the last few years of his life, when Mr. Dolin faced problems at work, he confided in his therapists.

You will see those therapists' notes and what Mr. Dolin was telling his therapists about his fears and anxieties, and they were recording what he told them.

The evidence will show that Mr. Dolin hid those thoughts and fears from his close friends. But what Mr. Dolin was telling his therapists was his reality; and in his mind, his worst fears were becoming real.

It is through those notes that we learn more about the real Stewart Dolin.

So that is the first and foremost question you must consider in this case: Why did Mr. Dolin take his own life. And the evidence will show that it was not because of Paroxetine.

The second question for you to consider is what is the scientific evidence regarding Paxil and suicide?

GSK has been looking into this issue since well before Paxil ever came on the market here in the United States in

1992.

I'm going to go through some of that scientific evidence quickly with you this afternoon, but you're going to hear about it in much greater detail from Dr. John Kraus, GSK's own scientist who was at GSK at the time when GSK did its most extensive suicide analysis. However, the evidence will show that Paxil does not cause suicide.

Third, did GSK communicate with the FDA, the United States Food and Drug Administration, the regulatory agency which controls which drugs are sold on the market as well as the labels that attach to those drugs.

Did GSK adequately communicate to the FDA and to doctors about the risks of Paxil?

The evidence will show that, yes, GSK definitely did communicate to the FDA and doctors. And when GSK did new studies or got new information, it told the FDA, and it worked with the FDA to change the label and to give doctors the information they needed to know.

Fourth and finally, was Mr. Dolin's doctor,
Dr. Sachman, his close friend that you've heard about, aware of
the possible risks of Paxil or Paroxetine?

The answer to that question is also a clear yes.

You will hear from Dr. Sachman, the Dolin's close friend and family physician, during this trial. You will hear that Dr. Sachman received and reviewed information from GSK

including about a risk of possible suicidal thoughts and behavior.

But even independent of what GSK told him, the evidence will be that Dr. Sachman knew of the possible risks if he started a patient on Paxil or Paroxetine. Not only did he know, but the evidence will show that he told both Mr. & Mrs. Dolin to watch out for any significant changes in Mr. Dolin's behavior after he started the medication.

His Honor said to you this morning before we began opening statements that you will be the ones to decide the disputed issues of fact. That means you and you alone are to determine what the evidence is most credible and most believable, most likely, and the one with the strongest support.

In the end, it's the plaintiff who must prove to you that Paroxetine caused Mr. Dolin to commit suicide. We don't have to prove what caused Mr. Dolin to commit suicide. But it's clear when you look at all the evidence Paroxetine did not.

In order to answer the first question, Ladies and Gentlemen, we need the talk about anxiety and depression.

Anxiety and depression are serious medical problems that affect millions of people in this country.

The evidence will be that untreated depression is itself the single biggest risk factor for suicide.

You're going to hear in this courtroom from GSK's expert psychiatrist, Dr. Anthony Rothschild. Dr. Rothschild will say that people commit suicide whether they're on the medication or not on any medication, and have been committing suicide as long as history has been recorded, long before medications like Paxil and others ever came on the market.

Suicide happens to the rich and famous, and suicide happens to everyday people.

In 2010, the year Mr. Dolin committed suicide, there were close to 40,000 suicides in the United States. Unfortunately, that's 1 suicide every 14 minutes. And in Illinois alone, there were an average of three suicides per Regrettably, Mr. Dolin was one of those suicides.

I'm going to spend a lot of time talking to you about Stewart Dolin, as this case is about him.

Mr. Dolin's increasing anxiety led his close friend Dr. Sachman to prescribe him antidepressant medications on several occasions in the last few years of his life.

Mr. Rapoport told you a little bit about Mr. Dolin's ongoing mental health issues, but I'm going to tell you what he didn't tell you. I'm going to tell you the rest of the story.

> MR. RAPOPORT: Objection, your Honor.

THE COURT: Proceed.

MR. BAYMAN: Mr. Rapoport told you how Mr. Dolin was an elite partner at a big law firm, but the evidence will show

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that's not how Mr. Dolin saw himself.

We know from the therapists' records that, although Mr. Dolin did a good job of hiding it, in reality Mr. Dolin had extreme fears and severe anxiety, mostly driven by what was happening at work. He had these extreme fears and severe anxiety even when he was doing well and making a lot of money.

Now, Mr. Rapoport told you that Dr. Sachman was the first health care professional to ever treat Mr. Dolin for any anxiety or depression; but, actually, the evidence will show that Mr. Dolin's first treatment for anxiety and depression that we know of began in 1989 when he saw a psychiatrist named Dr. Roth after he joined the Sachnoff & Weaver law firm.

Mr. Dolin treated with Dr. Roth for over seven years between 1989 and 1996 in both individual and group therapy.

In 1990 the Dolins and Dr. and Mrs. Sachman became friends. They became good friends. You're going to hear how they socialized together, vacationed together, their families spent time together. Thereafter, Dr. Sachman became the Dolin's family doctor.

Then in October 2005, Dr. Sachman first prescribed Paroxetine for his friend Mr. Dolin at the same 10 milligram dosage that he later prescribed Paroxetine in 2010.

Mr. Dolin filled 13 months' worth of prescriptions of Paroxetine, from 2005 to 2006 -- that's 390 pills, Ladies and Gentlemen -- and not once did he complain to Dr. Sachman or any

other health care professional about any problems with the medication. He stopped taking generic Paroxetine in late 2006.

But 2007 brought a lot of change to Mr. Dolin and high levels of anxiety.

First, his Chicago law firm that you heard about, Sachnoff & Weaver, a one-office, 140-lawyer Chicago firm, announced in the fall of 2006 that it was going to merge in to the global law firm Reed Smith, a law firm with 1,500 lawyers with 20 offices all around the world. It was not a merger of equals, Ladies and Gentlemen. Reed Smith was more than ten times bigger. Mr. Dolin's firm was being absorbed into Reed Smith, and it would become Reed Smith's 21st office.

You will learn that Mr. Dolin was the leader or chair of the business department, a group of corporate lawyers within Sachnoff & Weaver. And when his firm merged into Reed Smith, Mr. Dolin was asked to co-lead the Corporate & Securities group, or C & S group, with a Reed Smith partner in California named John Iino.

Shortly after the announcement of the merger, but before it became final in February of 2007, Mr. Dolin sought treatment from a social worker named Sydney Reed. Ms. Reed was a colleague of the plaintiff Wendy Dolin, who herself is a social worker.

At Mr. Dolin's first visit, Mr. Dolin shared how the structure of his new firm was radically different from his old

1 | firm and how that caused him anxiety.

He told Ms. Reed that he had anxiety about the merger with Reed Smith in part because, although he went to Loyola, a prestigious law school, he didn't go to Harvard or Yale, and he didn't feel qualified to work at Reed Smith.

His first job was at an eight-person law firm, and now he was joining a 1,500 law firm -- 1,500-lawyer law firm. And as he says to Ms. Reed and she records in her note, he never had strong mentors that helped him practice at a sophisticated level.

Mr. Dolin returned to Ms. Reed a week later on February 26th, 2007, when he -- at which time he told her he can't sleep, he was having a hard time holding it together, he wanted to get up and run. Mr. Dolin also reported that being scared by the thought of not supporting his family.

And right after Mr. Dolin reported these concerns to Ms. Reed, the Reed Smith merger happened.

After the merger took place, on May 14th, 2007, Mr. Dolin told Sydney Reed he felt like he was in a completely different world.

You will hear from Mr. Dolin's law partners in this trial who will note the magnitude of the change for the Sachnoff & Weaver attorneys.

After the merger, Mr. Dolin told Ms. Reed that he was afraid that fear will make him stop functioning.

The very next week, on May 26th, 2007, Mr. Dolin went back to Ms. Reed, and he told her that he was frozen and afraid of his professional life. He was asking what shall I do?

In early June, June 2nd of 2007, Mr. Dolin told
Ms. Reed he was feeling passive about what was happening and
that he never had a backstop financially.

In mid-June, on June 16th, 2007, that same month, Mr. Dolin told Ms. Reed about lots of insecurities that he had always had. She noted need to contain his anxiety.

These comments and other comments that you'll hear during this trial that Mr. Dolin made to his therapists are important because they candidly reveal what he was thinking at the time but was hiding from other people.

They are also important because these same fears resurfaced in 2010 when some real-life events occurred that made these fears seem like they were coming true.

The evidence will also show that Mr. Dolin was unable to get through this period with therapy alone due to his increased fears and severe anxiety.

So he went back to Dr. Sachman, and Dr. Sachman treated Mr. Dolin with another medication, Sertraline, what Mr. Rapoport called generic Zoloft, from June 2007 until 2009.

Mr. Dolin took 1,000 Sertraline pills, over 600 days, and he never reported any problems with that medicine to any of his doctors, including his close friend Dr. Sachman.

Instead, he started to become more optimistic. He reported new opportunities at work. And as you'll see on this slide, there's some examples of the more hopeful tones in Mr. Dolin's visits to Ms. Reed in that summer and fall.

For example, on October 7, he reports he's been reaffirmed in his leadership, and then Ms. Reed noted that he's doing well.

The evidence will also show that on November 10th, he says he recognizes he can survive hell.

However, as Mr. Dolin faced year-end pressures at work at the end of that year, his first year at Reed Smith, in December of 2007, Mr. Dolin went back to Ms. Reed and told her that he had suicidal thoughts. It was his first year at the new firm, and he was co-leading the group, but his group had missed their budget by \$6 million.

The merger had caused his life to change completely.

He had extreme fears and severe anxiety about being able to perform in the new firm and keep his job.

Ms. Reed explored those suicidal thoughts with Mr. Dolin, and the evidence will be she determined they were connected to his end-of-the-year work pressures.

However, Mr. Dolin never told his close friend

Dr. Sachman or anybody else about those suicidal thoughts.

In fact, as Mr. Rapoport pointed out, Mr. Dolin went to see Dr. Sachman two weeks later on December 15th for a

check-up, and he made no mention of any mental health issues, let alone any thoughts of suicide.

At the start of 2008, Mr. Dolin appeared to be doing better, financially, at work, and in therapy sessions to the point that he stopped seeing Ms. Reed in June of 2008.

Now, as you may recall, the economy took a turn for the worst in late 2008, and this directly impacted Mr. Dolin's professional world.

In 2009 Mr. Dolin became the sole chair of Reed Smith's Corporate & Securities Practice group because Mr. Iino, his cochair, had gotten a promotion and moved to a higher rank in the firm.

In this new role, given these tough economic times, Mr. Dolin had to lay off attorneys, including the son of a very close family friend. And his group failed to meet their budget this time by \$30 million.

That brings us to 2010. In his own self-evaluation, which he did at the end of the year -- he did about the end of his year 2009 and prepared this in 2010, he described 2009 as without a doubt been my most challenging year ever in my professional career. He said in his own words the economy played havoc with the practices of so many lawyers in C & S, Corporate & Securities, including my own.

Early in 2010, Mr. Dolin also reviewed -- learned of reviews from other lawyers in his practice group about his

performance as practice group leader. They called him a terrible practice group leader. Not motivational. Said he had an utter lack of knowledge. Played favorites. Called him arrogant. Non-responsive and deceitful. Another comment called Mr. Dolin a middle market lawyer from a middle market firm.

Regarding these reviews, you will hear from John Iino that Mr. Dolin forwarded these reviews to Mr. Iino and said somebody out there doesn't like me.

The point of this evidence is not to tell you that Mr. Dolin was a bad person. Not at all. Instead, the evidence will be that these comments tie into Mr. Dolin's longstanding fears that he wasn't qualified to work at Reed Smith.

Then in February 2010, Mr. Dolin learned that he was getting a six-figure pay-cut. Now, don't get me wrong, Mr. Dolin still made very good money. But this pay-cut came as a shock to Mr. Dolin. His compensation had never been cut before. In fact, Mr. Dolin appealed his pay-cut to Reed Smith's leadership.

Mr. Dolin described the firm's decision to lower his compensation as a seismic shock to him.

This is his compensation appeal to the leadership of Reed Smith.

He told the firm leadership that the compensation cut was not warranted. But Mr. Dolin's appeal was unsuccessful.

Now, you're going to hear from Mr. Dolin's law partner, Paul Jaskot, one of the witnesses, as Mr. Rapoport mentioned, who has testified under oath by videotape -- by videotaped deposition, and it will be played to you.

Mr. Jaskot is going to tell you that this pay-cut was very upsetting to Mr. Dolin. And because of the way the Reed Smith law firm shared their data, Mr. Dolin's partners were actually able to see his compensation cut so that all the partnership knew his compensation had been cut.

Following the review and the pay-cut, at the end of April 2010, Mr. Iino told Mr. Dolin that he wanted to name a much younger partner, Paul Jaskot, as Mr. Dolin's cochair to manage the C & S group with him.

Mr. Jaskot had worked as a vice chair under Mr. Dolin, but now they were to be equals.

Mr. Dolin told others, including his wife, his friends, his law partner and good friend Mike Lovallo, that he had requested the change because he wanted to focus on his own law practice. But you'll hear Mr. Iino say that the change was not Mr. Dolin's idea, it was Mr. Iino's idea. The evidence will show that Mr. Iino wanted Mr. Jaskot to be in the position because he had more confidence in Mr. Jaskot. Mr. Iino will tell you that himself.

After the appointment of Mr. Jaskot as cochair in May of 2010, Mr. Dolin went back into treatment with his therapist

1 | Sydney Reed.

On May 20th, 2010, Mr. Dolin again brought up the same issues that he had complained of in his compensation appeal.

It was still bothering him.

He complained about the fact that he had spent enormous amount of time managing the group, yet he got his pay cut. He was asked, Ms. Reed noted, what does he want to do.

Mr. Dolin was trying to figure it out, Ladies and Gentlemen.

The evidence will show you that he asked those questions about what he should do because his pay had been cut, he had now a much younger partner as cochair who was now his equal.

On June 3rd, Mr. Dolin returned to Ms. Reed. She notes that he was confused about his job and uncertain about leaving or staying at Reed Smith. She notes he was not enjoying being practice group leader.

You'll hear from Ms. Reed by videotape, as

Mr. Rapoport mentioned, talk about the similarities between
what happened in 2007 and what was currently happening in 2010.

But the evidence will show that what was different this time around was that, unlike in 2007, in 2010 Mr. Dolin's fears were actually starting to come true, or at least in his mind they were. He had negative reviews, a six-figure pay-cut, and the appointment of a younger cochair. In fact, Mr. Reed noted -- Ms. Reed noted that he was highly anxious and said the

old fear loop was triggered.

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Now, Mr. Dolin wasn't taking any antianxiety or antidepressant medications when he told Ms. Reed about his increasing fears and severe anxiety in May of June -- May and June of 2010.

In late June 2010, Mr. Dolin's close friend

Dr. Sachman started him again on Sertraline, the same

medication Dr. Sachman had put Mr. Dolin on from 2007 to 2009,

due to stresses from work and stress-related anxiety. But this

time Mr. Dolin complained to Dr. Sachman that he had a minor

complaint, such as nausea, so he only took it for a short time.

The evidence will show, Ladies and Gentlemen, that whenever Mr. Dolin experienced issues with his medication, he did not hesitate to tell his close friend Dr. Sachman.

Then on June 22nd, 2010, Mr. Dolin went to Ms. Reed and told her that he thinks he's painted himself into a corner. She noted he's getting very busy, but he's convinced he can't do the work. She noted he wanted excuse to curl up in the corner and that the fear of failure puts him in a position of not even trying.

The evidence will show that these are the same fears that he expressed three years earlier when he was not taking any medication at all.

Then on June 29th, Mr. Dolin went to see a clinical psychologist that Mr. Rapoport told you about, Dr. Seoka

1 | Salstrom.

Dr. Salstrom completed an intake form with Mr. Dolin at this first visit.

Less than three weeks before he took his own life, Mr. Dolin reported he had been experiencing anxiety at work, well before he had restarted any medication, and that he felt this way for the last month and a half. He told Dr. Salstrom that he didn't feel clear in his mind. He was worried that he would make a mistake or that something bad could happen and leave him penniless.

Most importantly, Ladies and Gentlemen, when Dr. Salstrom asked him, what would he want if she could have a magic wand, he said no stress. When she says I have a magic wand and I can make things go away, he says no stress.

At this visit Mr. Dolin was not taking any antianxiety or any depression medication.

You'll hear Dr. Salstrom say that she recorded that same session client described longstanding history of fears -- feelings of insecurity at work with some noted anxiety/worry episodes during major mergers and responsibility changes.

Remember, he had just gone through a merger, and he just had a change in responsibility.

Mr. Dolin also told Dr. Salstrom of the many stressors he was experiencing at work, which no doubt included some of the issues I've already mentioned to you.

But what he didn't tell Dr. Salstrom, Ladies and Gentlemen, was that he had had suicidal thoughts in the past, specifically on December 1, 2007, the note that I showed you earlier, when he confided in Mrs. Reed about his suicidal thoughts. In fact, Dr. Salstrom note -- noted no history of depression or suicidal ideation, which is suicidal thinking, or attempts.

At the end of this visit, Dr. Salstrom gave Mr. Dolin a questionnaire to fill out. She said fill this out and bring it to me in your next session. But he didn't do that. And you'll hear why that's important in a few minutes.

Now, you're going to hear from Dr. Salstrom by videotaped testimony in this trial, and she's going to tell you about the types of therapy that she does and how that differed from the therapy methods used by Ms. Reed.

Dr. Salstrom's therapy method is designed to get a patient to confront their anxieties, to bring it all out, and then to act, whereas Ms. Reed's therapy is designed to lessen anxiety.

The evidence will show that Dr. Salstrom believes that a patient should not be exposed to both methods at the same time. In fact, Dr. Salstrom told Mr. Dolin that he should stop treating with Ms. Reed if he was going to continue to see her, Dr. Salstrom.

You're going to hear also videotaped deposition

testimony from Ms. Reed. The evidence will show that Ms. Reed was also concerned about Mr. Dolin working with two different therapy methods, and she agreed they were conflicting, they could create confusion for the client, and most importantly they could cause a heightened state of anxiety.

But the evidence will show that Mr. Dolin continued to see both therapists. But, unfortunately, the therapists were not coordinating with each other, nor were they communicating with Dr. Sachman.

A week later at a second visit to Dr. Salstrom on July 6th, 2010, Mr. Dolin again expressed worries and said he thought I'm a bad lawyer, incompetent.

These are the same types of fears and anxieties that Mr. Dolin was expressing to Ms. Reed back in 2007 when he was not on any antianxiety or antidepressant medication.

Mr. Dolin -- Mrs. Dolin testified that -- earlier in this case, and we expect she'll testify here, that Mr. Dolin started taking generic Paroxetine on Saturday, July 10.

The evidence will show that Dr. Sachman recorded that it was for increased work-related anxiety.

Listen to Dr. Sachman's testimony when he testifies.

He recalled that Mr. Dolin had done well on Paxil in the past,
and that's why he prescribed Paroxetine again in 2010.

After Mr. Dolin restarted generic Paroxetine, the stress at work did not let up. He had a difficult meeting

coming up that Friday with one of his clients, Miniat, Inc.

Also the evidence will show that Mr. Dolin was upset with Reed Smith because they had filed a lawsuit that he had thought would adversely affect one of his largest client relationships. He was worried that he might lose that client.

That Monday evening, believing he had major client problems, Mr. Dolin had his third and final visit with the psychologist, Dr. Salstrom. Dr. Salstrom noted Mr. Dolin had many avoidance tendencies, especially at work. She further noted that he got distracted by worry thoughts during the session and that Mr. Dolin was stuck in worry.

The evidence will also show, Ladies and Gentlemen,
Mr. Dolin continued to avoid filling out that questionnaire
that Dr. Salstrom had given him at his first visit on June 29th
when he denied having any suicidal -- any history of suicidal
ideation or attempts.

On his second visit, he again had not completed that questionnaire.

But it's during this third visit that Mr. Dolin finally admitted to Dr. Salstrom that he hadn't filled out that questionnaire since June 29th due to fear of passive suicidal thoughts.

And having finally admitted that, it's important to note that the evidence will show that from June 29th through July 9th Mr. Dolin was not on any antianxiety or antidepressant

medication on any of those days.

Mr. Dolin's anxiety was increasing and his problems at work were growing.

In fact, on Wednesday morning, the day before he committed suicide, Mr. Dolin, as Mr. Rapoport said, out of his customary practice, reached out to Ms. Reed to schedule a visit for that night.

Ms. Reed reported he was very upset, anxious, worried about failing Wendy -- that's Mrs. Dolin -- and getting fired. She noted he had a wish not to wake up. No plan.

The evidence will show that his longstanding fears were starting to happen. These records reflect a consistent theme that he expressed over the years when he was worried and anxious even before he started work at Reed Smith.

You will hear Ms. Reed describe Mr. Dolin's anxious demeanor during that visit, hear her explain that Mr. Dolin had said he was worried about a difficult meeting that Friday at work -- that was the meeting with the Miniat clients -- and you will hear her talk about this final visit.

On the morning of July 15th, Mr. Dolin got up as usual, he worked out on the elliptical machine at his home, he drove to the Metra station in Glencoe where he lived, he took the train to work to the Ogilvie station, he stopped at Starbucks, he participated in some conference calls and he met with Mike Lovallo his partner for 45 minutes that morning. He

asked Mr. Lovallo to join him at a meeting with the Miniat client the next day at which there was to be a shareholder vote, which was a controversial proposal. Mr. Lovallo said it didn't make sense for him to attend that meeting and Mr. Dolin should attend alone.

While they were meeting, Susan Kolavo, Mr. Dolin's client at Miniat, sent an email postponing that shareholder vote because Mr. Dolin had failed to do the work the company had requested of him.

He took a few more calls, and later that morning Mr. Dolin received a call from Ms. Reed that Mr. Rapoport told you about who told him to call his family doctor to get a fast-acting antianxiety medication to calm him down based on the behavior she had seen at the session the night before.

But Mr. Dolin didn't call Dr. Sachman.

Mr. Dolin attended a scheduled lunch with a business acquaintance, Terry Schwartz.

While Mr. Dolin was at lunch, Kevin Miniat, a family member and shareholder of Miniat, Inc., sent an email expressing his anger about the postponement of the shareholder vote. In this email, Kevin Miniat clearly states: This is not acceptable.

That email came in at 12:11 p.m. And Mr. Dolin returned from lunch around 12:45 p.m.

Mr. Dolin left his office around 1:15 and walked to

the Blue Line Washington Station, a CTA train.

Now, Ladies and Gentlemen, we don't know how -- what route he took to get there, but his office was here, the Ogilvie Transportation Center, which is his normal train station for the Metra train that he took into work and home from work was here, and he walked over here. He would have had to pass -- he would have had to navigate summer crowds and traffic. Although we don't know exactly how he proceeded, what route he took, he would have to go by a closer, either by or under, a closer train station at Washington and Wells. But, instead, we know that Mr. Dolin walked to the Blue Line station over here. That's not a station that he normally used as a Metra rider.

He went to the station, he purchased a ticket, and he went through the turnstile. He waited for the train. And, unfortunately, as the train approached, Mr. Dolin deliberately jumped in front of the train and took his own life. His cell phone and his wallet were not found among his personal effects after his death.

Now, Ladies and Gentlemen, the evidence will show that the decision to take his own life was Mr. Dolin's and Mr. Dolin's alone and had nothing to do with Paroxetine. In fact, we don't even know how many pills of Paroxetine Mr. Dolin even took. We believe at most it was six pills, if he took it as prescribed. But we will never know how many pills Mr. Dolin

took because the evidence will show that Mrs. Dolin threw the pill bottle away shortly after his death.

Now, Mr. Rapoport mentioned an eyewitness on the train platform who said that Mr. Dolin was pacing shortly before his death. But in response to an email requested by Mrs. Dolin, that eyewitness, Mr. Pecoraro, sent an email stating Mr. Dolin's behavior on the train platform was the type routinely seen of individuals waiting on public transportation, nor would it be surprising for someone who was about to end his own life to be pacing right before he did it.

You will hear Mr. Pecoraro say Mr. Dolin was pacing and agitated as he stood on the platform, but Mr. Pecoraro will also say this behavior was not uncommon, not unusual, and not out of the ordinary for somebody waiting on a train.

You will hear we expect in this case the plaintiff's expert, who has testified at deposition and we expect he will testify here, say that Mr. Dolin had a condition called akathisia which was induced by Paxil and caused Mr. Dolin to commit suicide.

Not one doctor or health care provider he saw in his final week ever diagnosed him or suggested that he had akathisia. You're only going to hear about akathisia from the plaintiff's expert hired and paid for by Mrs. Dolin's lawyers.

However, you will hear from a number of people who interacted with Mr. Dolin that last week, and none of them

observed any symptoms to support the plaintiff's claim.

Dr. Salstrom, one of his therapists who saw him the Monday before, Dr. Sachman himself, his close friend and doctor, had dinner with the Dolins on Tuesday night, less than 48 hours before Mr. Dolin committed suicide. Dr. Sachman will testify that Mr. Dolin was calmer than he was, and even offered Dr. Sachman advice about a problem Dr. Sachman was having. When asked if Mr. Dolin had akathisia, Dr. Sachman testified only if I did. He was calmer than I was.

Dr. Sachman, Ladies and Gentlemen, is a trained medical professional, and he didn't see any signs of akathisia, nor did either Wendy Dolin nor Mr. Dolin say anything to Dr. Sachman that night about any problems Mr. Dolin was experiencing on the medication.

Sydney Reed, one of Mr. Dolin's therapists who saw him the night before he took his own life, saw no evidence of behavior consistent with what would be akathisia.

Mike Lovallo, Mr. Dolin's law partner and close friend, he described Mr. Dolin as calm the morning of his suicide compared to the way Mr. Dolin was earlier in the week. Mr. Lovallo had met with Mr. Dolin for 45 minutes that morning about the client issues that Mr. Dolin was facing.

Laura Krueger, Mr. Dolin's long-time secretary, who interacted with him all week, she said she noticed nothing out of the ordinary that week.

And, finally, Terry Schwartz, the business associate who Mr. Dolin had lunch with an hour before he took his own life. Mr. Schwartz will testify by videotaped deposition that Mr. Dolin was calm, coherent, and acting like he always had during that lunch.

Therefore, the only person who discusses any changes in Mr. Dolin's behavior, the evidence will show, is Mrs. Dolin.

Plaintiff claims that Mr. Dolin had akathisia that was induced by Paxil, but somehow wants to ignore the increasing stresses, work problems, and longstanding history of severe anxiety.

The evidence will show that Mr. Dolin's major fears and stresses from 2007 were becoming real in his mind right before he took his own life.

The evidence will show that plaintiff could not prove that Mr. Dolin had akathisia or that Paroxetine caused him to commit suicide.

And now, Ladies and Gentlemen, that brings us to our second question:

What is the scientific evidence regarding Paxil and suicide?

There have long been medications to treat anxiety and depression; but for the class of medications called SSRIs -- and you heard a little bit about that from Mr. Rapoport -- that's the class of medicines that includes Paxil, Prozac,

Zoloft, Celexa, those other medications, those earlier medications had severe side effects, dizziness, blurred vision, side effects so bad that patients simply stopped taking the medicines.

Paxil and the other SSRIs had much fewer side effects and allowed people with depression and anxiety to get out of bed, go to work, lead normal lives, spend time with their family, and be productive.

The evidence will show in this case, Ladies and Gentlemen, that antidepressants worked for Mr. Dolin.

Paxil has been thoroughly tested for its safety and effectiveness by both GSK and the FDA, and no study has ever shown that Paxil causes suicide.

The FDA first approved Paxil back in 1992, and Paxil has been available to patients ever since.

In fact, between 1992 when the FDA first approved Paxil and in 2004, FDA approved Paxil and its controlled-release formula Paxil CR as safe and effective 13 different times.

Paxil was originally approved to treat major depressive disorder, but over time it was studied to treat other mental health disorders and approved by the FDA for each of the disorders that you see here in front of you on the screen.

But what's important about that, Ladies and Gentlemen,

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for each of these additional approvals, each time FDA approved the medication for what is called a new indication or a new disorder, the FDA had to make a new decision. It had to review all of the safety data that had accumulated on Paxil from the date of the original approval in 1992 up through the date of the most recent approval. This included GSK's clinical trial data, information from patients and doctors, scientific literature from researchers studying Paxil, FDA had to review it all. And because the medication had been taken by thousands of -- thousands more patients since the last approval, the FDA had to make a new decision each time as to whether this new accumulated additional information about the medication still confirmed that Paxil was safe and effective and that its benefits still outweigh its risks. And every time FDA approved Paxil for a new indication, FDA also had to review and approve the label.

Because, Ladies and Gentlemen, the evidence will be in this case that at the end of the day the FDA is the ultimate authority on what goes in a prescription drug label. The FDA ultimately must approve the label. A manufacturer cannot sell a prescription medication in this country without an FDA-approved label.

In every one of those 13 times, FDA said: Yes, Paxil was safe and effective. FDA said: Yes, Paxil's benefit outweighed its risks. And FDA said: Yes, the Paxil label was

1 appropriate.

As I mentioned earlier, the evidence will show that untreated depression is the single biggest risk factor for suicide.

Now, the concern about any depressant medications and suicide has been around as long as the medications themselves. And that's not surprising, because depressed or anxious people are at the greatest risk for suicide. And, unfortunately, even with treatment, some of those patients do go on to commit suicide.

As a result, GSK, independent researchers, and the FDA itself have continued to monitor the issue of Paxil and suicidality, and none of the clinical trial data has ever shown that Paxil causes suicide.

Additionally, while it's listed as a possible side effect, no study has ever shown that akathisia causes suicide.

Now, you've heard in Mr. Rapoport's opening and from me even the term "clinical trial." And I'd like to talk to you about that for a moment as it's a term we're going to hear a lot about in the coming weeks.

Mr. Rapoport showed you a little bit about it. I want to explain a little bit more.

What is a randomized clinical trial you might ask.

Well, clinical to the FDA regulators means humans.

At the beginning of a trial, a randomized clinical

trial, the patients are enrolled in the trial, and they go through roughly a two-week period called the placebo run-in or wash-out period. You'll hear both of those terms. That's a phase where they're given placebo or sugar pills to allow other medications literally to wash out of their systems.

Randomized means that a group of patients with similar characteristics are divided into two groups.

That's the next phase of the trial. That is the controlled phase, because patients take the medications under the watchful eye of doctors.

One group is given Paxil; the other group is given placebo or a sugar pill.

But here's the important thing: In the controlled phase, the Paxil pills and the placebo pills look the same.

The patients don't know which pills they're receiving, nor do the doctors know. And that helps to eliminate bias.

The records identifying which pill, Paxil or placebo, are sealed or what's called blinded until after the clinical trial is over.

Then the records are unblinded at the end of the trial. And the patients are then -- in the two groups are measured depending on which pill they were given.

The results of the controlled phase of the two groups are compared on two fronts.

First, the researchers measure the medication's effect

on the underlying condition being treated, such as anxiety or depression.

And what they look at is for the Paxil patients is does Paxil improve the mental health condition being studied compared to the patients in the placebo group? In other words, is it beneficial? Does Paxil work? Does it treat the condition that the patients are suffering from? Is it effective? Does it do what it's supposed to do?

But even if the medication works, Ladies and Gentlemen, the researchers and doctors look to see do its benefits outweigh its possible side effects, its so-called adverse events.

Now, Ladies and Gentlemen, the evidence will be that all prescription medicines have risks. That's why they're available only by a doctor's prescription.

The doctors involved in the clinical trials, the M.D.s who are actually treating these patients, are directed to check and to record each and every single complaint of anything unusual or unpleasant that happens while the patient is on either the medication or placebo.

The doctor does not have to believe that the medication caused the side effect. He or she records everything the patient reports, and that includes literally everything a patient might complain of.

The evidence will be, Ladies and Gentlemen, that even

patients taking a sugar pill or placebo complain of side effects.

In the controlled phase, Ladies and Gentlemen, the researchers are looking to see if there's what's called a statistically significant difference between any side effects or adverse events on patients taking the medication versus what the patients on placebo are experiencing.

The reason this is done is to determine if certain adverse events or side effects need to be warned about in the prescription label.

You will hear from GSK's expert statistician, Dr.
Robert Gibbons, from right here at the University of Chicago,
who will explain this process to you in much more detail.

Once the controlled phase of GSK's Paxil trials were over, some trials allowed patients to stay on Paxil because the medicine worked for them. This is what's often called the extension phase of the trial. But in this phase, there are no patients on placebo, the placebo patients are done, so there's nothing to compare against, and the doctors and the patients know that they are on the medication.

Ladies and Gentlemen, the evidence will show that the medical community, including the FDA, regard the results of randomized clinical trials, the process I just mentioned, as the gold standard, the best evidence available on the risks and benefits of a prescription medication.

Now, you've heard Mr. -- you heard Mr. Rapoport spend more than 60 minutes criticizing GSK about what it did with its data.

But what GSK did back in 1991 was to capture all the clinical trial data, to capture all events from the very beginning of the clinical trials in the run-in or the wash-out phase to the very end of the trials in the extension phase.

And it gave all that data to FDA, because in 1991, when a manufacturer submitted what's called a new drug application -- that is the application to get approval to sell the medicine -- the practice was to submit all of the data, no matter when the event occurred during the trial.

And the evidence will show that the FDA knew that run-in events were being included in that data and that the FDA did its own independent analysis of that data.

Now, at one point Mr. Rapoport said GSK did not tell FDA about the suicide run-ins. Then he showed you a document submitted to the FDA that showed the exact opposite.

But, Ladies and Gentlemen, again, this is -- this was 1991 he was talking -- he's talking about. And you'll hear evidence about why the word "randomized" was put in quotes and what that meant. You'll also hear that GSK disclosed that events from the run-in and the wash-out were counted, as well as events from the extension phase when there was no placebo arm to compare, as well as from trials on patients that didn't

take placebo, trials against other medications, and so forth.

But, Ladies and Gentlemen, science evolves. And years later, what the FDA said matters is only the controlled data, the data from the controlled phase of the placebo controlled trials that I showed you.

In 2002, eight years -- in 2002, before Mr. Dolin ever took any Paroxetine pills, and eight years before Mr. Dolin committed suicide, GSK went back and looked at that 1991 data Mr. Rapoport showed you. GSK re-analyzed that original suicide data to look at only the controlled phase of those clinical trials where there was a placebo comparator, an apples-to-apples you will hear. And when it did, when it looked at the data, head-to-head, it found no significant difference between the Paxil group and the placebo group on the question of does Paxil cause suicide.

Mr. Rapoport mentioned an 8 times -- 8.9 times increased risk, but the only way his experts can get to that number is to count data from the third phase, the extension phase, where there's no placebo group to compare with, or to look at non-placebo controlled trials.

But the FDA has made it very clear. The FDA only wants to study data from the controlled phase of placebo controlled trials.

So throughout this trial, every time you hear about a study or analysis, you need to ask yourself: Is it placebo

controlled? Because if not, that's not the data the FDA relies upon and has not relied upon for over ten years.

Ladies and Gentlemen, Mr. Rapoport did not go into this in much detail, but I feel that I need to tell you more of the story.

In 2006, in its largest analysis to date, GSK analyzed all of the adult clinical trial data from all of the randomized controlled trials of Paxil. They reviewed that data for a number of different things.

On the main question they were looking at, does Paxil cause suicidal thoughts or behaviors in patients taking Paxil for depression or anxiety disorders, there was no evidence of any increased risk.

A few years earlier, GSK had done an analysis of 14,000 adult patients from the Paxil clinical trials. And in this analysis, GSK broke the data out by specific age group, including a group of those patients aged 50 to 59, an age that would include 57-year-old Stewart Dolin. When that group was analyzed, those patients taking Paxil had a lower rate of possibly suicide-related events compared to those taking a placebo.

In other words, it was protective, which means that Paxil actually reduced the risk of suicide in patients in Mr. Dolin's age group.

And, Ladies and Gentlemen, the evidence will be that's

not surprising. Paxil treats depression and anxiety. And depression and anxiety are big risk factors for suicide.

FDA -- Mr. Rapoport mentioned this briefly -- FDA also analyzed the issue of suicide or suicidality in adult patients taking Paxil and other antidepressants.

In 2006, several months after GSK's analysis, FDA did its own analysis of Paxil and other antidepressants. It was the FDA's largest analysis ever.

Mr. Rapoport talked for more than an hour about the run-ins and the data from '89 and '91, and he talked for about five minutes about this analysis, but it's important, because FDA found no increased risk on the main question of suicidal thoughts or behavior. This was in 2006, Ladies and Gentlemen. A much greater, more robust body of data had been developed by 2006 than existed back in 1989 and 1991.

FDA's analysis showed that in adults aged 25 to 64, that is within Mr. Dolin, who was 57 age group, antidepressants have a neutral or possibly even protective effect, and the older the patient, the stronger the protective effect.

This is FDA's conclusion, Ladies and Gentlemen, analyzing all the data from all the antidepressants.

And as for Paxil specifically, on its primary analysis, FDA found no increased risk of suicidal thoughts or behavior for adults taking the medicine.

Now, Mr. Rapoport told you that Paxil was the only

SSRI with a statistically significant increased risk, but what he didn't tell you is that the FDA itself said you cannot rely on that finding.

And perhaps the biggest point here is the evidence will show that the FDA was aware of the Paxil finding because it was the FDA's very own analysis.

Mr. Rapoport showed you an article from Dr. Juurlink in Ontario. FDA was aware of that article and decided not to include it in its subsequent warnings.

Now, Mr. Rapoport tried to point you to some secondary analysis as if they mean more than they do. He talked about a subgroup of patients with a specific diagnosis called major depressive disorder, or MDD, who attempted suicide. But what he didn't tell you is that those 11 patients, the denominator in that study was 3,455 patients. That's one-third of 1 percent or 0.03. That means, even in this one subgroup analysis, 99.6 of the Paxil patients did not have suicide attempts.

I expect you'll hear more about this analysis as the trial goes on, but you should know of those 11 patients, 8 were between the ages of 18 and 30, and several had thought or even attempted suicide before they ever took Paxil.

Dr. John Kraus, who I mentioned is GSK's scientist, who you'll hear about live, looked at the case histories for those 11 patients in great detail, and he will tell you that

not one of them went on to commit suicide.

That brings us to our third question, Ladies and Gentlemen:

Did GSK communicate with the FDA and doctors about the possible risks of Paxil?

The evidence will show that the answer to that question is also definitely yes.

When GSK did new studies or got new information, it told the FDA, and it worked with the FDA to make sure the labeling was appropriate and doctors knew what they needed to know.

But before I get into the labeling, I want to clarify one point.

You might be asking yourself, well, if Paxil doesn't cause suicide, why is a possible risk of suicide even warned about in the label?

Pharmaceutical companies include warnings and precautions in their medications labeling so doctors can weigh the risks and benefits when prescribing medication, even when it's not clear that the medication is causing the risk. This way the doctor has a more complete picture of what to watch for when he or she treats a patient.

The label that we're talking about, Ladies and Gentlemen, is not what you get at the pharmacy when you pick up your prescription, that summary. The label is a detailed

technical document that is intended for doctors so that they can educate themselves about developments, advancement, and information about the medicine. The label is important.

So I'm going to show you the changes that were made to the Paxil label over the last decade, because Mr. Rapoport told you that GSK never included any information in the label about Paxil and suicide.

Ladies and Gentlemen, the evidence will be otherwise.

I'm going to show you the label changes as they evolved. I'm going to show you the changes GSK was allowed to make and the changes that FDA would not allow GSK to make.

So let's start in April 2004. This is over a year before Dr. Sachman first prescribed Mr. Dolin Paroxetine.

GSK changed the Paxil labeling to specifically warn -it's right here on your screen -- patients being treated with
antidepressants should be observed closely for clinical
worsening and suicidality, especially at the beginning of a
course of drug therapy.

Now, FDA required all antidepressants include this same language. And that's referred to as class labeling. FDA required the group or the class of antidepressant medications -- I mentioned some of them already, Prozac and Zoloft, Paxil, Celexa -- to have identical language on this subject.

The labeling in 2004 also warned that akathisia, which

the labeling described as psychomotor restlessness, had been reported in patients treated with antidepressants, and this language was also required by the FDA as class labeling, meaning all the antidepressants had to have this same language.

After noting akathisia and other symptoms had been reported by patients, the language in the labeling in 2004 went on to state: Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients for whom such symptoms are severe, abrupt in onset, and were not part of the patient's presenting symptoms.

So the FDA says causation has not been established, it's not been established the drug causes suicide, but you should be on the lookout for these things.

And all of this language, Ladies and Gentlemen, was required by the FDA as class labeling for all the antidepressants, including Paxil.

The labeling starting in 2004 went on to warn that families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and non-psychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, and the other symptoms described

above, what I just showed you, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers.

You will hear evidence in this case from Dr. Sachman, Ladies and Gentlemen, that he knew about this, and that he told both Mr. & Mrs. Dolin let me know if there are any significant changes in behavior after Mr. Dolin starts on the medicine.

This language was also class labeling required by the FDA of all antidepressant manufacturers.

The next month, in May of 2004, GSK sent a communication out to doctors across the country. That's what's called a Dear Healthcare Provider Letter, and you'll hear about those in this case, in which it provided that same information that was in the label to doctors. The evidence will show that this letter was sent to Dr. Sachman and that Dr. Sachman had a practice for reviewing these kinds of letters.

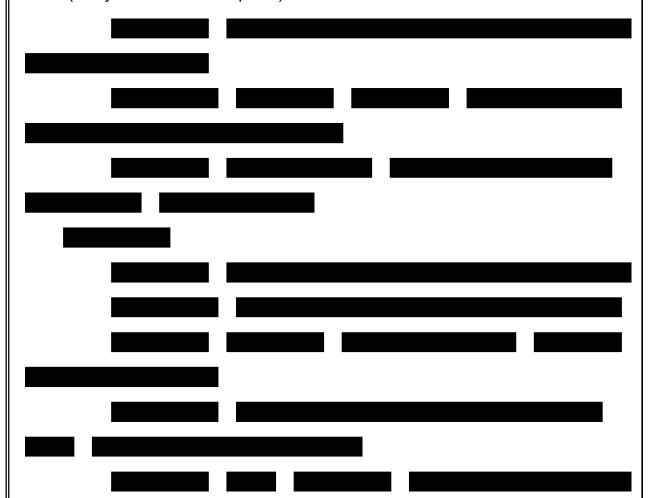
The letter then attached a copy of the warning or clinical worsening of suicide risk as well as the new precaution on information for patients, which is the language that I just showed you. And I'm not going to go back over it. It's what I just showed you that was in the warning.

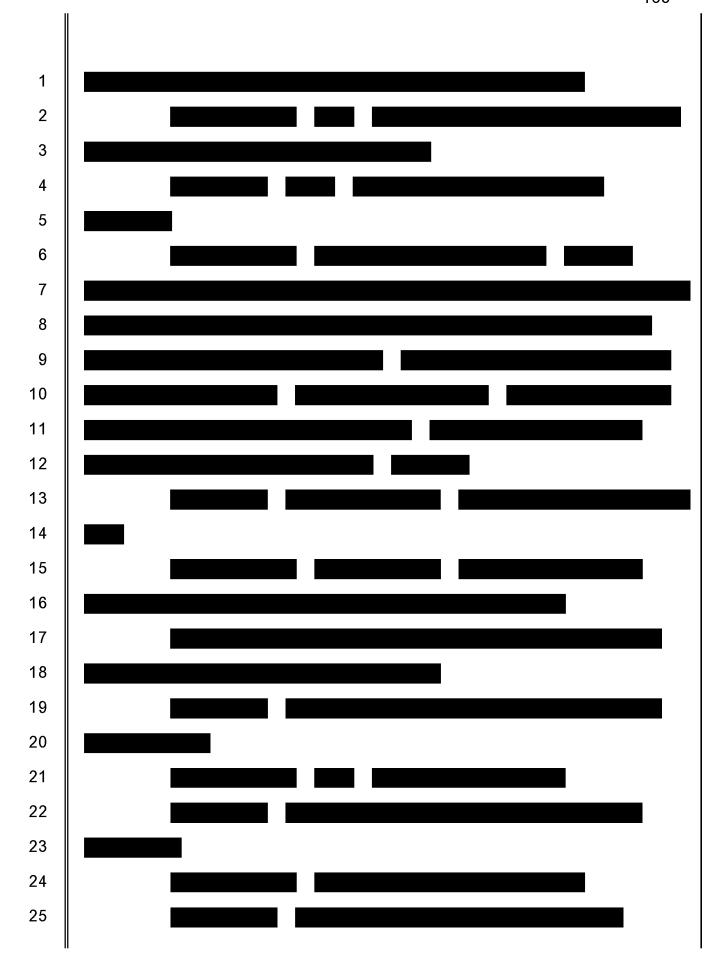
Then in early 2005, FDA required GSK to revise the Paxil label slightly so the language more closely resembled the language put in what's called a black box warning for all antidepressants regarding the concern of suicidality with the

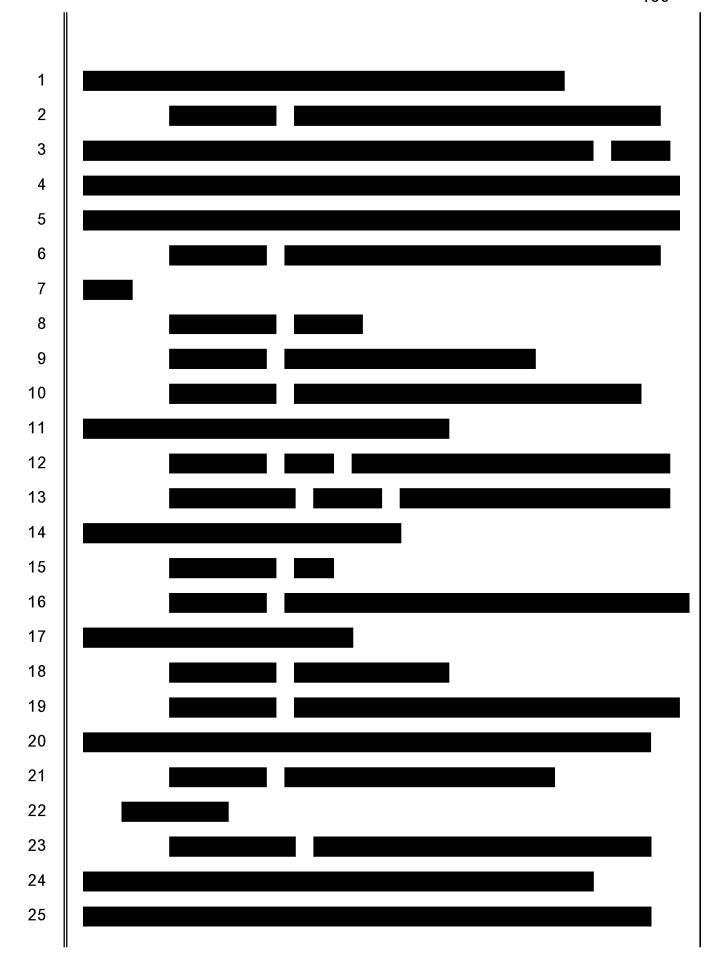
use of antidepressants in patients under 18. THE COURT: Okay. Mr. Bayman, I believe now we're going to break. MR. BAYMAN: Sure. Thank you, your Honor. Good time. THE COURT: All right. Ladies and Gentlemen, remember all of my admonitions to you when you go home tonight. Don't forget us now, and come back here tomorrow morning ready to proceed at 9:30. I'll have coffee and rolls for you in the jury room by 9:00 o'clock.

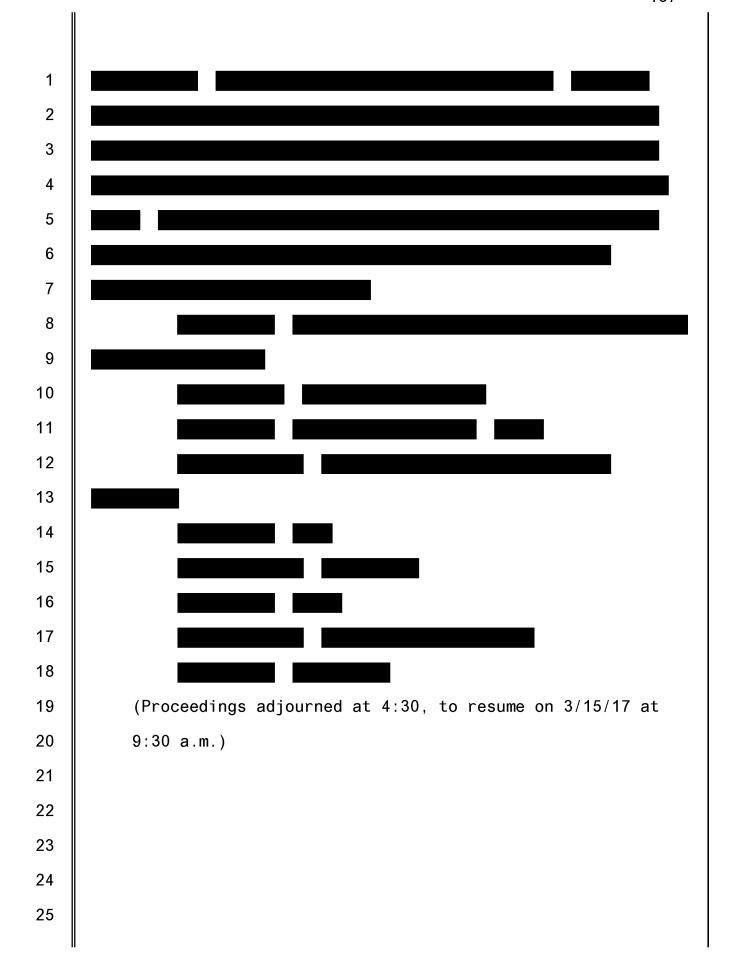
Thank you very much. Have a good evening.

(Jury out at 4:26 p.m.)









1	CERTIFICATE
2	
3	We, CHARLES ZANDI and GAYLE A. McGUIGAN, certify that the
4	foregoing is a correct transcript of the record of proceedings
5	in the above-entitled matter.
6	
7	
8	/s/ CHARLES ZANDI <u>March 14, 201</u> 7 CHARLES ZANDI, CSR, CRR
9	Official Court Reporter
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11	
12	<u>/s/ GAYLE A. McGUIGAN</u> <u>March 14, 201</u> 7 GAYLE A. MCGUIGAN, CSR, CRR
13	Official Court Reporter
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