

THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF ORANGE

- - -

BEVERLY SMITH, on behalf of herself)
 and all others similarly situated)
 and on behalf of the general public,)
)
 Plaintiff,)
)
 vs.) Case No.:
) 04 CC 00590

SMITHKLINE BEECHAM)
 CORPORATION, dba GLAXOSMITHKLINE, a)
 Pennsylvania Corporation, and DOES)
 1-100, inclusive,)
 Defendants.)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

- - -

PAMELA BLAIN, Individually and as)
 Personal Representative of the Estate)
 of TREVOR KYLE BLAIN, II, Deceased, and)
 on Behalf of All Those Similarly)
 Situated; TONYA D. Brooks, Individually)
 and on Behalf of ALL of Those Similarly)
 Situated; RONALD BLAIN, Individually;)
 LEX BROOKS, Individually; Cheryl Brooks,)
 Individually)
)
 Plaintiffs,)
 vs.) Case No.:
) 06-1247-JD

SMITHKLINE BEECHAM CORPORATION d/b/a/)
 GLAXOSMITHKLINE, a Pennsylvania)
 Corporation,)
 Defendant.)

DEPOSITION OF
NEAL RYAN, M.D.
PITTSBURGH, PENNSYLVANIA
OCTOBER 5, 2006

ATKINSON-BAKER, INC.
COURT REPORTERS
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FILE NO.: A008101

Page 2	Page 4
<p>1 STATE OF MINNESOTA 2 COUNTY OF HENNEPIN 3 - - - 4 Leigh Ann Eng, Darcene and Greg) 5 Lensing, on behalf of the general 6 public, themselves and all others) 7 similarly situated) 8 Plaintiffs,) 9 vs.)Court No: 10)PI-04-012879 11 SMITHKLINE BEECHAM CORPORATION,) 12 d/b/a/GLAXOSMITHKLINE, a) 13 Pennsylvania corporation,) 14 Defendants.) 15 ----- 16 17 Deposition of NEAL RYAN, M.D., taken on behalf 18 of the Plaintiffs at Professional Suites, US Steel 19 Tower, Suite 600, 600 Grant Street, Pittsburgh, 20 Pennsylvania, commencing at 9:14 a.m., Thursday, 21 October 5, 2006, before Michele A. Kohar, Certified 22 Court Reporter. 23 24 25</p>	<p>1 I-N-D-E-X 2 WITNESS: NEAL RYAN, M.D. 3 EXAMINATION PAGE 4 BY MR. MURGATROYD 9 5 BY MR. DAVIS 109, 270 6 EXHIBITS PLAINTIFFS PAGE 7 DESCRIPTION 8 41- Presentation of Neal Ryan 11 9 Pfizer symposium in Barcelona 10 April 1999 11 42- Presentation of Neal Ryan 14 12 Grand Rounds, University of 13 Texas in Galveston, Department 14 of Psychiatry July 1999 15 16 43- 10/03/98 e-mail from 17 17 J. McCafferty to N. Ryan 18 19 44- ENCP Poster 19 20 45- Presentation of Neal Ryan 23 21 University of Belfast, Northern 22 Ireland October 1999 23 46- Presentation of Neal Ryan 30 24 Cornell Medical School 25 March 2000 47- Presentation of Neal Ryan 32 American College of Psyconeuropharmacology December 2000 48- Presentation of Neal Ryan 34 Cold Spring Harbor February 2001</p>
<p>1 A P P E A R A N C E S 2 3 FOR THE PLAINTIFFS: 4 BAUM HEDLUND 5 BY: GEORGE W. MURGATROYD ESQUIRE 6 12100 Wilshire Boulevard, Suite 950 7 Los Angeles, California 90025 8 9 FOR THE DEFENDANTS: 10 KING & SPAULDING 11 BY: TODD DAVIS, ESQUIRE 12 1180 PEACHTREE STREET 13 ATLANTA, GEORGIA 30309 14 15 FOR THE DEPONENT: 16 UNIVERSITY OF PITTSBURGH 17 OFFICE OF GENERAL COUNSEL 18 BY: PAMELA W. CONNELLY, ESQUIRE 19 1710 Cathedral of Learning 20 Pittsburgh, Pennsylvania 15260 21 22 23 24 25</p>	<p>1 49- Presentation of Neal Ryan 35 2 National Alliance on Mental 3 Illness July 2001 4 50- SBK Final Clinical Report 51 5 Issue date 11/24/98 6 7 51- Presentation of Neal Ryan 62 8 9 52- Presentation of Neal Ryan 63 10 American Psychiatric Association 11 Meeting May 2002 12 13 53- 6/13/04 e-mail from 68 14 M. Keller to D. Carpenter 15 16 54- 6/13/04 e-mail from 68 17 M. Keller to N. Ryan 18 55- 6/13/04 e-mail from 68 19 M. Keller to Ryan, Strober 20 Emslie, Wagner 21 56- 6-10-04 e-mail from 68 22 D. Carpenter to Keller, 23 Wagner, Emslie, Ryan, Strober 24 57- 6-9-04 e-mail from 68 25 M. Keller to N.Ryan/M. Strober/K. Wagner/G. Emslie 58- 2/4/04 e-mail from 80 N.Ryan to M.Keller/M.Strober cc: K. Wagner 59- 2/04/04 e-mail from 81 N. Ryan e-mail to P. Pereva/E. Wetherhold 60- 3-16-04 e-mail from N. 88 Ryan to M.Keller/P. Perera 61- 1/5/06 Memorandum from 90 Department of Health 62- 1/30/04 CSPI letter 99 63- Information Document (Redacted Pg. 99,line 5)</p>
Page 3	Page 5

Page 6			Page 8		
1	64- 11-19-95 Progress Report	103	1	PITTSBURGH, PENNSYLVANIA; THURSDAY, October 5, 2006;	
2	65A- 11-8-02 e-mail from N. Ryan to M. Keller	106	2	9:14 A.M.	
3			3	VIDEOGRAPHER: Good morning. This is	
4	65B-1/4/06 Memorandum to N. Ryan from D. Steed	106	4	October 5, 2006 at approximately 9:14 a.m. The	
5			5	videographer is Martin Murray of Investigative	
6	66- SKB 9/11/98 Final Investigator Audit Report		6	Videography, 121 Glenwood Avenue, Pittsburgh,	
7			7	Pennsylvania, 15209.	
8	EXHIBIT DEFENDANT'S PAGE		8	We are located at 660, USX Tower,	
9	DESCRIPTION		9	Pittsburgh, Pennsylvania 15219. We are here to	
10	1- Childhood & Adolescent Depression. A Review of the Past 10 Years.	111	10	videotape the continuance of Day Two of the	
11			11	deposition of Dr. Neal Ryan to be used at time	
12			12	of trial or for any other reason in the	
13	2 - JAACAP literature	122	13	Superior Court for the State of California, the	
14	3 - JAACAP literature	122	14	County of Orange, Case Number 04-CC-00590. We	
15	4 - JAACAP literature	122	15	have Beverly Smith, et. al, Plaintiffs versus	
16	5 - Keller Article literature	122	16	SmithKline Beecham et. al Defendants.	
17	6 - Keller Article literature	152	17	Also in the United States District Court	
18	7 - Keller Article literature	155	18	for the Eastern District of Pennsylvania Case	
19	8 - Keller Article/conclusion	157	19	Number 06-1247JD. We have Pamela Blain, et. al	
20	9 - Letters to the editor	182	20	Plaintiffs versus SmithKline Beecham	
21	10- Draft O1 rebuttal letter	182	21	Corporation, et. al, Defendants.	
22	11- PAR 329 Rebuttal	193	22	Also in the State of Minnesota, County	
23	12- 7-27-02 letter to M. Keller from M. Dulcan.	195	23	of Hennepin, District Court Fourth Judicial	
24			24	District, Court File Number PI-04-012879 we	
25	13- Letters to the editor	201	25	have Leigh Ann Engh, et. al, Plaintiffs versus	
	14- Review /Evaluation Clinical Data	212			
	15- Skating to Where the Puck Article	219			
Page 7			Page 9		
1	16- Psychopharmacology Bulletin	226	1	SmithKline Beecham, et. al, Defendants.	
2	17- 12-98 RE: Study 329	229	2	At this time would counselors please	
3	18- None (See pg. 230, line 5)	NONE	3	identify themselves and who they represent.	
4	19- 2-11-99 letter to S.Laden from J. McCafferty.	229	4	MR. MURGATROYD: My name is Skip	
5			5	Murgatroyd and I represent the Plaintiffs in	
6	20- Study 329 Draft	229	6	each of these actions.	
7	21- 3-30-99 e-mail to N.Ryan from G.Clarke	229	7	MS. CONNELLY: Pam Connelly representing	
8			8	Dr. Neal Ryan.	
9	WITNESS WAS INSTRUCTED NOT TO ANSWER		9	MR. DAVIS: Todd Davis representing	
10	(NONE)		10	GlaxoSmithKline and also present, but not	
11	INFORMATION TO BE SUPPLIED:		11	entering an appearance, is Amor Esteban from	
12	(NONE)		12	Drinker & Biddle.	
13			13	VIDEOGRAPHER: Please proceed.	
14			14	Neal Ryan, M.D.	
15			15	having been previously sworn, was examined	
16			16	and testified as follows:	
17			17	EXAMINATION	
18			18	BY MR. MURGSTROYD:	
19			19	Q. Good morning, Doctor.	
20			20	A. Good morning. 09:14:33	
21			21	Q. You understand you're still under oath?	
22			22	A. Yes.	
23			23	Q. Okay. And I understand that after the	
24			24	deposition concluded yesterday you went to look for	
25			25	the slides that you thought you may still have 09:14:44	

Page 10	Page 12
<p>1 regarding the presentations you've given on Paxil in 09:14:44 2 the treatment of depression, youth with depression?</p>	<p>1 Barcelona. This one, unlike the large majority of 09:17:44 2 the others, was sponsored by a pharmaceutical 3 company. This is sponsored by Pfizer.</p>
<p>3 A. I went to look for the presentations I've 4 given. Some of the presentations were not primarily 5 about that, but did include a couple slides on 09:14:58 6 Paxil. They were about larger topics. I brought 7 all of those.</p>	<p>4 Q. Okay. 5 A. So I prepared the slides on this entirely 09:17:50 6 of my own preparation. They did format the slides. 7 They did not tell me what content to present. They 8 didn't edit my slides.</p>
<p>8 Q. Okay. And I'm going to mark some of them 9 for the record and ask you to take a look at them, 10 and I believe your Counsel -- or actually that's 09:15:13</p>	<p>9 Q. Is that document authentic? 10 A. Yes. 09:18:11</p>
<p>11 fine. It's easier -- well -- I'm trying to think of 12 the most efficient way of doing this. I'm going 13 leave the tags on the different pages that I've 14 tagged. Do you see that?</p>	<p>11 Q. And, again, you created that, correct? 12 A. I created that document from the Power 13 Point slides from that talk, yes.</p>
<p>15 A. Sounds good. 09:15:33</p>	<p>14 Q. And at that presentation, did you discuss 15 paroxetine in the treatment of adolescents? 09:18:20</p>
<p>16 Q. Okay. And before I do that, in terms of 17 these presentations, what was the purpose of these 18 presentations? Did they vary from presentation to 19 presentation or did they generally have the same 20 purpose for each one? 09:15:50</p>	<p>16 A. Yes. 17 Q. Okay. Who were -- only had the symptoms 18 of major depressive disorder or for all types of 19 illnesses?</p>
<p>21 A. The purpose of all of them are -- well, 22 basically the purpose of them was to present 23 scientific data in the field that I was describing, 24 which was primarily the treatment of depression or 25 treatment -- diagnoses, treatment and course, and 09:16:05</p>	<p>20 A. The data that we had in this was -- the 09:18:33 21 only data available was what I presented, was the 22 study we've been referring to as 329. There were no 23 other paroxetine studies available in the world at 24 the time so that's what all I presented.</p>
<p>25 Q. Okay. And what did you in that 09:18:48</p>	<p>25 Q. Okay. And what did you in that 09:18:48</p>
Page 11	Page 13
<p>1 psychophysiology depression in some of them. 09:16:05 2 So larger topics about depression in 3 children and they included some data on Paxil trials 4 and typically the other antidepressant trials in 5 children. 09:16:16</p>	<p>1 presentation, what did you state the results of your 09:18:50 2 study were?</p>
<p>6 Q. Okay -- and -- 7 A. I'm sorry. I took a pause there. It 8 sounded like I had stopped.</p>	<p>3 A. I don't keep any -- I don't -- the slides 4 are obviously shorthand for what you talk about. 5 Q. Sure. 09:18:59 6 A. So all I have at this point are the 7 slides.</p>
<p>9 These were all presented -- every one of 10 them were presented to audiences of primarily 09:16:22 11 psychiatrists and psychologists, child 12 psychiatrists, all to professional audiences and 13 they were presented as scientific presentations.</p>	<p>8 Q. Right. 9 A. So the slides that I have related to the 10 paroxetine study. Our first slide that describes -- 09:19:05 11 it's a slide entitled "Paroxetine Multi-Site 12 Adolescent MDD Study.</p>
<p>14 (Ryan Deposition Exhibit No. 41 15 was marked for identification.) 09:17:16</p>	<p>13 Q. That's study 329? Correct? 14 A. That's correct.</p>
<p>16 Q. Let me show you what I've marked as 17 Exhibit 41.</p>	<p>15 Q. Okay. And I'm just looking for the 09:19:16 16 results of the efficacy.</p>
<p>18 MS. CONNELLY: For the record, this is 19 titled Presentation of Neal Ryan. It's dated 20 April 1999. 09:17:35</p>	<p>17 A. Right. So it has -- it's a single slide 18 that discusses paroxetine out of six times -- you 19 know, something like 50 or 60 slides here and it 20 has -- so there's one single slide discussing 09:19:29</p>
<p>21 BY MR. MURGATROYD:</p>	<p>21 paroxetine. It has four bullet points. The first 22 bullet point says: It was an 8 week randomized 23 trial. The second bullet point describes the dosage 24 that was given in the three treatments; paroxetine, 25 imipramine and placebo. The third point says 09:19:41</p>
<p>22 Q. Doctor, can you identify for the record 23 what that document is, please?</p>	<p>22 bullet point says: It was an 8 week randomized 23 trial. The second bullet point describes the dosage 24 that was given in the three treatments; paroxetine, 25 imipramine and placebo. The third point says 09:19:41</p>
<p>24 A. Yes. It's a presentation that I did for a 25 symposium for psychiatrists. It was held in 09:17:43</p>	<p>24 that was given in the three treatments; paroxetine, 25 imipramine and placebo. The third point says 09:19:41</p>

<p style="text-align: right;">Page 14</p> <p>1 paroxetine was superior to placebo on measures of 09:19:44</p> <p>2 effect, global improvement and remission of</p> <p>3 depressive symptoms, and the fourth point says</p> <p>4 imipramine not superior to placebo on any outcome</p> <p>5 measures. 09:20:01</p> <p>6 Q. Okay. Thank you. Let's go to the next</p> <p>7 one. So in that presentation you did not come out</p> <p>8 and say that Paxil is effective for the treatment of</p> <p>9 adolescents with major depressive disorder?</p> <p>10 Correct? 09:20:11</p> <p>11 A. To the best of my knowledge in all of</p> <p>12 these I gave a more balanced discussion, which was</p> <p>13 it worked that on some of the indicators and not on</p> <p>14 others. That would have been scientifically</p> <p>15 correct. 09:20:22</p> <p>16 (Ryan Deposition Exhibit No. 42</p> <p>17 was marked for identification.)</p> <p>18 MR. MURGATROYD: Okay. Let's look at the</p> <p>19 next one.</p> <p>20 THE WITNESS: So you get that one back, 09:20:28</p> <p>21 right?</p> <p>22 MR. MURGATROYD: Actually, the court</p> <p>23 reporter does.</p> <p>24 MS. CONNELLY: We leave it with this pile.</p> <p>25 THE WITNESS: Thank you. 09:20:28</p>	<p style="text-align: right;">Page 16</p> <p>1 A. Yes. 09:21:29</p> <p>2 Q. And it was prepared by you also?</p> <p>3 A. Yes.</p> <p>4 Q. And I noticed that -- and correct me if</p> <p>5 I'm wrong -- that incorporated slides that had been 09:21:31</p> <p>6 previously created from Martin Keller? Is that</p> <p>7 correct?</p> <p>8 MR. DAVIS: Object to the form; no</p> <p>9 foundation for that.</p> <p>10 THE WITNESS: It incorporated slides? I 09:21:48</p> <p>11 think that in fact it did incorporate a slide</p> <p>12 of -- let me look for it. The slide that</p> <p>13 was -- let's see -- I do not know that they</p> <p>14 were presented for Dr. Keller, but the two</p> <p>15 slides I believe that were prepared originally 09:22:07</p> <p>16 from -- by GSK were a slide that shows the maps</p> <p>17 of where the investigators were and the slide</p> <p>18 that shows the so-called, quote "study design",</p> <p>19 which shows the three arms. I used those</p> <p>20 because they contained the correct data, and it 09:22:18</p> <p>21 was easier than redoing them myself.</p> <p>22 BY MR. MURGATROYD:</p> <p>23 Q. Okay. And some of the balance of those</p> <p>24 slides were used by Martin Keller in</p> <p>25 earlier presentations, earlier than your? Correct? 09:22:33</p>
<p style="text-align: right;">Page 15</p> <p>1 MS. CONNELLY: The next one is a 09:20:28</p> <p>2 presentation dated July '99.</p> <p>3 BY MR. MURGATROYD:</p> <p>4 Q. Okay. And for the record, can you</p> <p>5 identify what that document is, please? 09:20:35</p> <p>6 A. Sure. This was an invitation to give</p> <p>7 grand rounds at the University of Texas in</p> <p>8 Galveston, the Department of Psychiatry, July '99.</p> <p>9 Q. And what, for the jury's purposes,</p> <p>10 edification, what is a grand round? 09:20:44</p> <p>11 A. Sure. A department will invite a scholar</p> <p>12 in some area to talk about their area of scientific</p> <p>13 research, typically, you know, 10 to 20 per year.</p> <p>14 Most of the department will attend that.</p> <p>15 Q. Okay. And this was actually where Dr. 09:21:07</p> <p>16 Wagner, one of your coauthors works, correct?</p> <p>17 A. That's correct.</p> <p>18 Q. Okay. And did she invite you down to give</p> <p>19 that lecture?</p> <p>20 A. It was Dr. Chris Thomas who's in the child 09:21:14</p> <p>21 division who works with Dr. Wagner invited me. I</p> <p>22 don't know whether she was in the chain of approval</p> <p>23 of that or not.</p> <p>24 Q. Okay. And that document is authentic,</p> <p>25 correct? 09:21:28</p>	<p style="text-align: right;">Page 17</p> <p>1 MR. DAVIS: Object to form. 09:22:33</p> <p>2 MS. CONNELLY: Object to form. There's no</p> <p>3 evidence in the record containing that</p> <p>4 assertion in your question.</p> <p>5 BY MR. MURGATROYD: 09:22:35</p> <p>6 Q. Well, I'm just -- do you recall that?</p> <p>7 A. I have no knowledge of whether Dr. Keller</p> <p>8 used these slides before I did.</p> <p>9 Q. Okay. Let's see if we can sort that out.</p> <p>10 A. Okay. 09:22:44</p> <p>11 VIDEOGRAPHER: Can we go off the record?</p> <p>12 MR. MURGATROYD: Sure.</p> <p>13 VIDEOGRAPHER: At this time we're going</p> <p>14 off the record. The time is 9:25 a.m.</p> <p>15 (Pause in Proceedings.) 09:23:26</p> <p>16 VIDEOOPERATOR: We are now back on the</p> <p>17 record. The time is approximately 9:25 a.m.</p> <p>18 (Ryan Deposition Exhibit No 43.</p> <p>19 was marked for identification.)</p> <p>20 BY MR. MURGATROYD: 09:24:05</p> <p>21 Q. Okay. Let me show you what I've marked as</p> <p>22 Exhibit 43.</p> <p>23 A. Okay.</p> <p>24 Q. And can you identify for the record what</p> <p>25 that document is, please, sir? 09:24:31</p>

Page 22	Page 24
<p>1 responsibility for it once it's in my 09:28:41 2 presentation. 3 BY MR. MURGSTROYD: 4 Q. Okay. So now at this grand rounds -- 5 again, that's where -- that's a gathering of 09:28:48 6 physicians, correct? 7 A. Yes. 8 Q. And would be also psychologists and social 9 workers and so forth? 10 A. Yes. Faculty members at the University of 09:28:52 11 Galveston, Texas. 12 Q. Okay. And obviously it's slides that are 13 projected onto the wall for -- that different people 14 see? 15 A. Right. 09:29:03 16 Q. So obviously the people, if they're paying 17 attention, saw the slide that said that Paxil is an 18 effective treatment for adolescents? Correct? 19 MS. CONNELLY: Object to the form. He 20 can't say what other people may or may not have 09:29:20 21 seen. 22 BY MR. MURGATROYD: 23 Q. Well, is available? That statement was, 24 available for all the people there to view, correct? 25 A. Yes. 09:29:24</p>	<p>1 slides. So some of the slides change. Some don't. 09:32:16 2 Q. Okay. Well, let's go to the ones that are 3 tagged there. Actually, before we do that, that 4 document is authentic, correct? 5 A. Yes. 09:32:26 6 Q. And you prepared that? 7 A. Yes. 8 Q. Okay. Great. Do you see where I have one 9 of the tags? 10 A. The first tag, yes. Which slide would you 09:32:31 11 like me to discuss? 12 Q. Is that the slide we discussed earlier? 13 Does that show the Martin Keller slide as being used 14 again in this presentation? 15 A. It was a slide representing work we had 09:32:44 16 done jointly; so yes, I was using a slide on work 17 we'd done jointly -- 18 Q. Okay. 19 A. -- correctly representing that work. 20 Q. Okay. Now, let's go to the next tag. The 09:33:01 21 second one, please? 22 A. Yes. 23 Q. Turning to the next page. 24 A. Okay. 25 Q. Okay. Does that have the results of -- 09:33:05</p>
<p>1 Q. Okay. Now, do you recall actually saying 09:29:24 2 those words too? 3 A. I typically don't read the words but talk 4 through them, but certainly. 5 Q. That's fine. Thank you. All right. 09:31:20 6 Let's go to the -- I think I got out of order. What 7 was the last one? 8 A. You have 42, 44 and 43. I think you're up 9 to 45. 10 Q. Thank you. 09:31:20 11 (Ryan Deposition Exhibit No. 45 12 was marked for identification.) 13 Q. Okay. Let me show you what I've marked as 14 Exhibit 45. Doctor, can you identify for the record 15 what that document is? 09:31:43 16 A. Yes. This was a grand round that I did at 17 the University of Belfast in Northern Ireland in 18 1999, and so I did a Multi-R presentation that 19 included all kinds of stuff including a little bit 20 on antidepressants in children -- and adolescents -- 09:32:01 21 my apologies. 22 Q. And in that presentation you included the 23 slides, I guess? Did you keep using the same slides 24 over and over again? 25 A. Certainly I don't remake most of the 09:32:14</p>	<p>1 did I do the tag? My apologies. Here we are. 09:33:07 2 Summary efficacy. Okay. Can you read that into the 3 record, please? 4 A. Sure: Summary-efficacy. Paroxetine 5 superior to placebo on measures of affect, global 09:33:14 6 improvement and remission of depressive symptoms. 7 Imipramine not superior to placebo in any outcome 8 measures. Paroxetine is an effective treatment for 9 MDD in adolescent outpatients. 10 Q. Okay. So that's the same slide that we 09:33:29 11 saw earlier, correct? 12 A. It's a slide -- it's a slide on work that 13 I had done that I represented as correct. It was 14 the best data available then and it was cited 15 correctly. It was a slide that we had seen earlier 09:33:35 16 in my work. It's different from the slide in the -- 17 in the thing you presented me from Dr. Keller only 18 in the title. 19 Q. Okay. And it says that paroxetine is an 20 effective treatment, correct? 09:34:03 21 A. Yes, which it was at the time that this 22 was written, I think, the best estimate of the data. 23 Q. Well, actually, at the time that was 24 written you were aware of the Study of 337? 25 Correct? 09:34:11</p>

Page 26	Page 28
<p>1 A. Yes. 09:34:11</p> <p>2 Q. Okay. And 377 clearly showed that Paxil</p> <p>3 was not effective? Correct?</p> <p>4 A. Not correct.</p> <p>5 Q. Okay. It showed that Paxil was not 09:34:18</p> <p>6 effective?</p> <p>7 A. Not correct.</p> <p>8 Q. Okay. Did 377 reach statistical</p> <p>9 significance with any of the primary efficacy</p> <p>10 variables? 09:34:26</p> <p>11 A. No, but it's obviously disingenuous and</p> <p>12 scientifically wrong to say that shows it's not</p> <p>13 effective.</p> <p>14 Q. Well, the study failed? Correct?</p> <p>15 MR. DAVIS: Object to the form. 09:34:37</p> <p>16 THE WITNESS: Actually, again, that brings</p> <p>17 back an issue we discussed before that a failed</p> <p>18 study has a different meaning than that.</p> <p>19 BY MR. MURGATROYD:</p> <p>20 Q. It's a negative study? 09:34:41</p> <p>21 A. It was a negative study, yes.</p> <p>22 Q. Negative meaning it didn't show efficacy</p> <p>23 to a statistically significant --</p> <p>24 A. That's correct. That's scientifically,</p> <p>25 scholarly and every way you want to look at it 09:34:58</p>	<p>1 A. Yes. 09:36:03</p> <p>2 Q. And can you tell the jury what akathisia</p> <p>3 is?</p> <p>4 A. Motor restlessness. Feeling that you've</p> <p>5 got to move. Feelings of being restless. 09:36:11</p> <p>6 Q. And does it have an internal component?</p> <p>7 A. I'm not sure what you mean.</p> <p>8 Q. Does -- well, you say motor restlessness.</p> <p>9 Can you have akathisia without --</p> <p>10 A. It could be the feeling of restlessness as 09:36:14</p> <p>11 well as the moving itself, yes.</p> <p>12 Q. Okay. And how does that -- a patient who</p> <p>13 experiences akathisia, is it a discomforting</p> <p>14 sensation?</p> <p>15 A. Yes. 09:36:33</p> <p>16 Q. And can it be severe?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And have you read the different</p> <p>19 medical literature that states that it could be</p> <p>20 associated with suicidality if left untreated? 09:36:44</p> <p>21 MR. DAVIS: Object to the form.</p> <p>22 THE WITNESS: I have read articles</p> <p>23 hypothesizing that this may be related to</p> <p>24 suicidality. To the best of my knowledge that</p> <p>25 is simply hypothesis with almost no supporting 09:37:01</p>
<p>1 different than strong evidence that it does work. 09:34:59</p> <p>2 It simply did not show that it did work.</p> <p>3 Q. Okay. And let's go to the second -- to</p> <p>4 the next tag I have on that document.</p> <p>5 A. Huh-huh. 09:35:11</p> <p>6 Q. And do you see that box right next to it</p> <p>7 that talks about extrapyramidal?</p> <p>8 A. Yes.</p> <p>9 Q. And what was the purpose of that box?</p> <p>10 A. The purpose of this box was to talk about 09:35:18</p> <p>11 one group of symptoms that you can get with all</p> <p>12 SSRIs in adolescents and adults. To remind them of</p> <p>13 that possibility.</p> <p>14 Q. Okay. And it --</p> <p>15 A. It was in with a group of slides -- where 09:35:29</p> <p>16 a number of slides I was talking about a number of</p> <p>17 side effects one can get with SSRIs. One more</p> <p>18 slide.</p> <p>19 Q. Okay. And are these side effects that are</p> <p>20 known to be caused by SSRIs? 09:35:46</p> <p>21 MR. DAVIS: Object to the form.</p> <p>22 THE WITNESS: These are side effects that</p> <p>23 are associated with SSRIs, yes.</p> <p>24 BY MR. MURGATROYD:</p> <p>25 Q. Okay. And is akathisia one of those? 09:35:59</p>	<p>1 data. 09:37:03</p> <p>2 BY MR. MURGATROYD:</p> <p>3 Q. Okay. Is that an issue that you've</p> <p>4 personally studied?</p> <p>5 A. We did systemically akathisia in these 09:37:09</p> <p>6 studies and that showed the rate of akathisia was</p> <p>7 very low. I don't remember that we had any in this</p> <p>8 particular study.</p> <p>9 Q. No. My question was: Did you -- have you</p> <p>10 personally studied the association between akathisia 09:37:16</p> <p>11 and suicidality?</p> <p>12 A. No. I read the literature.</p> <p>13 Q. Okay.</p> <p>14 A. I mean, I have not done a research study</p> <p>15 to address that question. 09:37:28</p> <p>16 Q. Okay. That's fine. And would you agree,</p> <p>17 sir, that Paxil can cause akathisia in some people</p> <p>18 who take it?</p> <p>19 MR. DAVIS: Object to the form.</p> <p>20 THE WITNESS: My knowledge of the 09:37:41</p> <p>21 literature suggests that all the SSRIs can</p> <p>22 cause it in some people who take it including</p> <p>23 Paxil.</p> <p>24 BY MR. MURGATROYD:</p> <p>25 Q. Okay. Thank you. Let's go to the next -- 09:38:29</p>

Page 30	Page 32
1 now I'm totally lost. Wait a minute -- 44, correct, 09:38:29 2 or I'm way out of order.	1 effective treatment for MDD in adolescent 09:39:50 2 outpatients."
3 MS. CONNELLY: Next is 46. 4 (Ryan Deposition Exhibit No. 46 5 was marked for identification.) 02:47:32	3 Q. Okay. So, again, this is the -- you're 4 using the same slide that -- it's the same message 5 that you had given in the earlier presentations that 09:40:11
6 BY MR. MURGATROYD: 7 Q. That's what I thought. Okay. Great. Let 8 me get rid of these.	6 paroxetine is an effective treatment for MDD in 7 adolescent outpatients, correct? 8 A. That's correct. That's a message I
9 Doctor, can you identify for the record 10 what that is? 09:38:31	9 thought was scientifically correct from all the data 10 available at the time. It's the same message. 09:40:24
11 A. This is a grand rounds that I did at 12 Cornell Medical School in March of 2000.	11 Q. Okay. So now let's go to the next Exhibit 12 which I'll mark as 47.
13 Q. Okay. Where is Cornell Medical School 14 located?	13 (Ryan Deposition Exhibit No. 47 14 was marked for identification.)
15 A. It's on the Harborside in Manhattan. 09:38:43	15 Q. Okay. And can you identify for the 09:40:50
16 Q. Okay. And, again, this is a grand rounds 17 where you're talking to other physicians?	16 record, sir, what this Exhibit is? 17 A. This is a slide presentation that I did
18 A. That's correct. I'm talking to faculty 19 and residents at Cornell.	18 for a talk at the American College of 19 Neuropharmacology in December of 2000.
20 Q. Okay. So that would be -- 09:38:59	20 Q. Okay. And is this document authentic? 09:41:07
21 A. It would be physicians, psychologists, 22 social workers, residents in psychiatry primarily.	21 A. Yes. 22 Q. And was it prepared by you?
23 Q. Okay. And also professors too, correct?	23 A. Yes.
24 A. Yes.	24 MR. DAVIS: Excuse me. Is it December of
25 Q. Okay. Now, how was it that you were asked 09:39:07	25 2000 or is there -- 09:41:14
Page 31	Page 33
1 to do this presentation. 09:39:11	1 THE WITNESS: There's two 09:41:18
2 A. I do not remember who invited me on that. 3 They -- again, they, you know, most departments of 4 psychiatry would have 10 to 15 grand rounds per year 5 and they simply invite different people to speak on 09:39:28 6 different topics as they think may be interesting.	2 separate documents. One is 2000 and one is 3 2003. 4 MR. DAVIS: Thank you, Dr. Ryan. 5 BY MR. MURGATROYD: 09:41:26
7 Q. Okay. And there's a tagged portion of 8 that slide presentation?	6 Q. And did you -- 7 MR. DAVIS: I don't have the 2000. That's 8 where I got thrown off. Oh, yes I do. I stand 9 corrected.
9 A. Yes.	10 BY MR. MURGATROYD: 09:41:33
10 Q. And, actually before -- that document's 09:39:37 11 authentic, correct?	11 Q. What is the American College of 12 Psychoneuropharmacology.
12 A. Yes.	13 A. It is a professional organization of
13 Q. And you prepared it?	14 senior researchers in psychiatry, psychopharmacology
14 A. Yes.	15 and basic neuroscience of psychiatric disorders. 09:41:44
15 Q. Okay. And you see the summary efficacy 09:39:43 16 box?	16 Q. Is it just researchers or is it also 17 doctors who actually go out and treat patients?
17 A. Yes.	18 A. Mainly researchers. Almost exclusively --
18 Q. Can you read that into the record, please?	19 to be a member you basically have to be a
19 A. Sure. Titled, Summary-Efficacy. Bullet 20 point one, "Paroxetine superior to placebo on 09:39:43 21 measures of affect, global improvement and remission 22 of depressive symptoms."	20 researcher. It would be very few clinicians. 09:42:03 21 Q. Okay. Can you also treat patients, also?
23 Bullet point two. "Imipramine not	22 A. Yes. Some of the people would treat
24 superior to placebo on any outcome measure."	23 patients.
25 Bullet point three, "Paroxetine is an 09:39:50	24 Q. Okay. And when you made this presentation
	25 was this funded by the ACNP? The American College 09:42:14

Page 34

1 of Psyconeuropharmacology is also known as the ACNP, 09:42:18
 2 correct?
 3 **A. That's correct.**
 4 Q. And was your trip funded by this
 5 organization? 09:42:24
 6 **A. I am trying to remember back. I was**
 7 **not -- if you remember, they don't fund anything.**
 8 **If you're not a member they pay \$500 towards travel**
 9 **costs which won't defray the whole cost. They don't**
 10 **give you any honorarium and I don't think I was a 09:42:43**
 11 **member yet. I am a member now. So either I got**
 12 **\$500 towards travel total, which would have been a**
 13 **net loss, but helpful, or I got nothing for it.**
 14 Q. Okay. And did you use the same slide in
 15 this presentation that said paroxetine is an 09:42:52
 16 effective treatment for MDD in adolescent
 17 outpatients?
 18 **A. Yes indeed.**
 19 Q. Okay. Let's go to the next one.
 20 (Ryan Deposition Exhibit No. 48 09:43:18
 21 was marked for identification.)
 22 Q. Have you had a chance to review it?
 23 **A. Yes.**
 24 Q. Okay. Can you identify it for the record
 25 please? 09:43:37

Page 35

1 **A. Yes. This is a presentation that I did at 09:43:39**
 2 **a retreat for investigators trying to understand**
 3 **child depression and anxiety disorders at Cold**
 4 **Spring Harbor in February of 2001.**
 5 Q. Okay. And, I'm sorry, can you repeat that 09:44:03
 6 again?
 7 **A. Sure. This was a retreat for**
 8 **investigators studying the question of child**
 9 **depression considered broadly at Cold Spring Harbor**
 10 **in February of 2001. 09:44:05**
 11 Q. How were people invited to that?
 12 **A. The cosponsors. They were the**
 13 **co-organizers of it. Boris Birmaher, and I'm**
 14 **forgetting the other one, decided which researchers**
 15 **to invite. 09:44:18**
 16 Q. Okay. And did you use the same slide in
 17 this presentation that we discussed earlier that
 18 says that Paxil is an effective treatment for MDD in
 19 adolescent outpatients?
 20 **A. Yes, indeed, because in February of 2001 09:44:33**
 21 **it still is the best data.**
 22 Q. Okay. Let's go to the next slide.
 23 (Ryan Deposition Exhibit No. 49
 24 was marked for identification.)
 25

Page 36

1 BY MR. MURGATROYD: 09:44:44
 2 Q. Okay. Can you identify for the record
 3 what that document is, please?
 4 **A. Yes. This is a presentation that I did at**
 5 **the request of the National Alliance on Mental 09:45:16**
 6 **Illness, which is a consumer organization of**
 7 **psychiatric -- an organization of psychiatric**
 8 **patients run by them in July of 2001.**
 9 Q. Okay. And by this time the results of 701
 10 were known, correct? 09:45:29
 11 **A. Not to me.**
 12 Q. Okay.
 13 **A. Or not to the world at large I believe.**
 14 Q. Okay.
 15 **A. Do you have any data that anybody else 09:45:41**
 16 **knew them at that point?**
 17 Q. I'm asking if you knew?
 18 MS. CONNELLY: No. Your question was as
 19 fact.
 20 THE WITNESS: You said they were known. 09:45:44
 21 BY MR. MURGATROYD:
 22 Q. Well, the results were completed. For --
 23 GSK had completed the study. That's what I meant.
 24 **A. But to your knowledge nobody else in the**
 25 **world knew it at that point so that was misleading, 09:45:58**

Page 37

1 **right? 09:45:58**
 2 Q. I asked: The results were completed? Do
 3 you understand the question?
 4 **A. No. You said the results were known at**
 5 **this point. 09:46:07**
 6 Q. Okay. So --
 7 **A. So that was clearly a misleading question,**
 8 **right?**
 9 Q. Well, I'm trying to find out whether or
 10 not you knew them? Did you know that? 09:46:09
 11 **A. You knew that I couldn't possibly know**
 12 **them at that time, right.**
 13 Q. Why? Why could you not know about it?
 14 You're out talking and telling people this drug's
 15 effective. GSK knows it's not. Don't you think you 09:46:16
 16 should have been told that?
 17 MS. CONNELLY: I'm going to have to object
 18 here. We're getting to the point of argument.
 19 Your fundamental first question was misleading
 20 in that it contained a fact which is not in 09:46:20
 21 evidence in this deposition.
 22 If you want to ask the straightforward
 23 question as to whether or not the witness had
 24 knowledge at the relevant time feel free to ask
 25 it. 09:46:33

<p style="text-align: right;">Page 38</p> <p>1 BY MR. MURGATROYD: 09:46:35</p> <p>2 Q. You were doing work with GSK?</p> <p>3 A. Not at this point, as you know.</p> <p>4 Q. Is that true?</p> <p>5 A. I was -- I don't think at this point I was 09:46:44</p> <p>6 doing any work with GSK, was I?</p> <p>7 Q. Well, let me ask you this: How did you</p> <p>8 find out the results of 377?</p> <p>9 A. They told me, but -- and we gave you the</p> <p>10 data on that one. 09:46:50</p> <p>11 Q. Oh, okay.</p> <p>12 A. And I saved all the net study and I told</p> <p>13 you that.</p> <p>14 Q. Okay. So you're saying GSK did not give</p> <p>15 you the data on 701? 09:46:59</p> <p>16 MR. DAVIS: Object to the form.</p> <p>17 THE WITNESS: Yes. They did not.</p> <p>18 BY MR. MURGATROYD:</p> <p>19 Q. And when did you find out about 701?</p> <p>20 A. We discussed that yesterday. 09:47:07</p> <p>21 Q. Then remind me.</p> <p>22 A. It was in the FDA report.</p> <p>23 Q. And not until the FDA report were you</p> <p>24 aware of 702's existence?</p> <p>25 A. To the best of my knowledge, yes. 09:47:18</p>	<p style="text-align: right;">Page 40</p> <p>1 MS. CONNELLY: He already testified. I 09:48:03</p> <p>2 never heard of it and now I know it's a</p> <p>3 consumer group, because he said it five minutes</p> <p>4 ago.</p> <p>5 BY MR. MURGATROYD: 09:48:07</p> <p>6 Q. Okay. I'm just clarifying. It's a</p> <p>7 consumer group, right? It's not physicians?</p> <p>8 A. Right. I think that's the third time.</p> <p>9 Yes, it's a consumer group.</p> <p>10 Q. Okay. I wanted to make sure I know who 09:48:11</p> <p>11 the audience is. So does the audience consist of</p> <p>12 consumers?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And how was it that you made this</p> <p>15 presentation? 09:48:20</p> <p>16 A. They invited me to give a talk to their</p> <p>17 audience, to their -- to the -- and these would be</p> <p>18 obviously to the representatives to the regional</p> <p>19 NAMI organizations and other interested NAMI</p> <p>20 members. 09:48:28</p> <p>21 Q. Okay. And did you give the same slide</p> <p>22 presentation regarding the -- with the statement</p> <p>23 that Paxil is an effective treatment for adolescents</p> <p>24 with MDD?</p> <p>25</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. And nor you were aware of those results 09:47:18</p> <p>2 until you read it from a source other than GSK?</p> <p>3 MR. DAVIS: Object to the form.</p> <p>4 THE WITNESS: I think I saw it first there</p> <p>5 and then on the GSK web site, but there was no 09:47:28</p> <p>6 data out there on 701 at the time.</p> <p>7 BY MR. MURGATROYD:</p> <p>8 Q. Do you believe that was important data for</p> <p>9 physicians such as yourself to have?</p> <p>10 MR. DAVIS: Object to the form. 09:47:41</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. MURGATROYD:</p> <p>13 Q. Okay. Now, referring -- going back to</p> <p>14 that exhibit right there.</p> <p>15 A. Yes. 09:47:43</p> <p>16 Q. What number is it again?</p> <p>17 A. Your Exhibit 49.</p> <p>18 Q. And you said that's a presentation before</p> <p>19 NAMI, N-A-M-I?</p> <p>20 A. That's correct. 09:47:48</p> <p>21 Q. And is that a consumer group?</p> <p>22 MS. CONNELLY: Asked and answered.</p> <p>23 THE WITNESS: Yes. That's correct.</p> <p>24 MR. MURGATROYD: Okay. I didn't ask if it</p> <p>25 was a consumer group. 09:48:03</p>	<p style="text-align: right;">Page 41</p> <p>1 MS. CONNELLY: Object to form. Are you 09:48:46</p> <p>2 asking him if the entire slide presentation was</p> <p>3 the same or whether that one particular</p> <p>4 efficacy slide was the same?</p> <p>5 MR. MURGATROYD: That one particular 09:48:58</p> <p>6 efficacy slide?</p> <p>7 THE WITNESS: Fine. Yes. I discussed a</p> <p>8 number of things including bipolar disorder,</p> <p>9 mood stabilizers, lithium, and I did, as you</p> <p>10 say, include the slide which we discussed 09:49:05</p> <p>11 before giving the details on the outcomes of</p> <p>12 the study in terms of which things it was</p> <p>13 superior on, and my overall assessment at the</p> <p>14 time is that it was an effective treatment.</p> <p>15 BY MR. MURGATROYD: 09:49:20</p> <p>16 Q. And in any of the slides that we've</p> <p>17 covered so far, did you tell your audience that</p> <p>18 Paxil had failed to reach statistical significance</p> <p>19 on the majority of the primary and secondary</p> <p>20 end-points? 09:49:28</p> <p>21 MR. DAVIS: Object to the form.</p> <p>22 THE WITNESS: That -- obviously a slide</p> <p>23 talk is a synopsis of the data. I think that</p> <p>24 the way -- the thing -- the quote "fact" you</p> <p>25 just presented is misleading and would have 09:49:41</p>

Page 42		Page 44			
1	mislead the audience, and so I was giving them	09:49:43	1	given to the audience?	09:52:01
2	my best professional opinion on how to		2	MR. DAVIS: Object to the form.	
3	summarize what the data meant.		3	THE WITNESS: Yes. But understand why I	
4	BY MR. MURGATROYD:		4	think that requires larger context, which is	
5	Q. Okay. You didn't answer my question so I	09:49:50	5	that --	09:52:07
6	move to strike it.		6	BY MR. MURGATROYD:	
7	My question was: Did you ever tell any of		7	Q. Doctor. Okay. You answered me.	
8	the audiences that we've discussed so far that Paxil		8	A. I need to answer your question. I am	
9	did not achieve statistical significance on the		9	giving you an answer which will be misleading if you	
10	majority of the primary and secondary end-points?	09:50:01	10	don't let me finish.	09:52:14
11	A. I think that would have mislead my		11	Q. I have one question for you.	
12	audience.		12	A. Okay. I'm still trying to finish the	
13	Q. So is the answer, you did not?		13	prior one, sir.	
14	A. I think that would have seriously mislead		14	Q. Go ahead. Finish it. Fine.	
15	the audience. I think one would have to be a	09:50:16	15	A. That this was the first time that anybody	09:52:20
16	complete idiot to tell people something like that.		16	had looked at those particular psychosocial outcome	
17	I did not.		17	measures in a direct depression treatment study, and	
18	Q. Thank you. Now --		18	the improvement in sort of psychosocial things tend	
19	A. I think it would be unethical to put		19	to lags the clinical improvement. So the fact that	
20	something that's misleading in a talk.	09:50:29	20	those were negative was a disappointment, but didn't	09:52:35
21	Q. I'm sorry. You think it would be		21	change the weight on whether this compound worked or	
22	unethical to tell an audience that Paxil failed to		22	not. So do you say to average those in? You know,	
23	achieve statistical significance on the majority of		23	that you have to average those in and you should	
24	the end-points that were predefined before the		24	have averaged those in? That's just wrong.	
25	breaking of the blind?	09:50:46	25	Q. Well, that's your opinion, and I think	09:52:50
Page 43		Page 45			
1	MR. DAVIS: Object to the form;	09:50:48	1	there's people that would disagree with you and I	09:52:52
2	mischaracterizes the data.		2	think you've read people who disagree with you,	
3	THE WITNESS: Yes. I don't think that is		3	correct?	
4	what the data showed. I think that -- I think		4	MS. CONNELLY: Objection. You're	
5	that -- I think that you have an obligation to	09:51:03	5	testifying now.	09:52:58
6	present fairly what the data showed and an		6	MR. DAVIS: I agree. Move to strike the	
7	obligation to give a fair conclusion so I think		7	last question.	
8	that twisting the data to make it -- to make it		8	BY MR. MURGATROYD:	
9	look worse than it was would be unfair. You		9	Q. Do you agree that people have disagreed	
10	can't -- if you present a whole paper you can	09:51:14	10	with what that just said in writing in journals?	09:53:03
11	have complicated discussions. When you're		11	MS. CONNELLY: Object to form; there's no	
12	doing a slide you have the obligation to get,		12	facts in evidence.	
13	you know, in two minutes in a talk that's 60		13	MR. MURGATROYD: Well, we'll get to it.	
14	minutes, to get the to stuff out there in a		14	MS. CONNELLY: There's factual assertions	
15	clear way.	09:51:26	15	embedded in that question.	09:53:11
16	BY MR. MURGATROYD:		16	BY MR. MURGATROYD:	
17	Q. Okay. So you think it was important to		17	Q. Fine. Do you agree with that, sir?	
18	tell the audience that it passed on three efficacy		18	A. I'm sorry? To the question again?	
19	variables? Right? That's what you have in this		19	Q. Do you agree that people, your colleagues,	
20	sticker slide?	09:51:37	20	disagree with the statement that you just made, and	09:53:18
21	A. I don't know. Let me go back and look. I		21	have made that in writing in journals?	
22	think we have four in there.		22	MS. CONNELLY: Object to the m; it embeds	
23	Q. Okay. And you don't think it was		23	factual statements which are not in evidence,	
24	important that all the other ones that it failed on,		24	and if you want to present a different question	
25	you don't think that information should have been	09:51:59	25	or evidence then he can answer that question.	09:53:26

	Page 46		Page 48
1	MR. MURGATROYD: He can answer that question. We'll present the evidence later. 09:53:26	1	MR. MURGATROYD: I understand. 09:55:11
2	3	2	MS. CONNELLY: -- and said it's 4 out of
3	MR. DAVIS: I join in that objection.	3	11, and now you're trying to say the witness
4	THE WITNESS: Fine. I am not aware of	4	was mischaracterizing it when it was your
5	anybody who disagreed with the statement I just made in writing. 09:53:37	5	question based on the paper. 09:55:16
6	7	6	MR. MURGATROYD: No. I'm not saying that.
7	BY MR. MURGATROYD:	7	In fact --
8	Q. Okay. We'll get to that. Now, remember	8	THE WITNESS: You said I mischaracterized
9	yesterday we talked about -- we added up the	9	it.
10	variables in your paper and it came up to 11? Do you recall doing that? 09:53:43	10	MR. MURGATROYD: No, I didn't. Those 11:59:58
11	12	11	weren't the words out of my mouth.
12	A. Yes.	12	MS. CONNELLY: I think. Let's just --
13	Q. Okay. And you testified only four of	13	MR. MURGATROYD: If you want to argue
14	those variables reached statistical significance in	14	about it that's fine.
15	favor of Paxil? 09:53:59	15	THE WITNESS: Fine. Read it back, please. 09:55:39
16	A. Yes.	16	MR. MURGATROYD: Doctor, you're not
17	Q. And we also talked about -- actually we	17	running this deposition.
18	talked about other variables that were analyzed	18	BY MR. MURGATROYD:
19	regarding that study that didn't make it into your	19	Q. How many variables --
20	paper, right? 09:54:11	20	MS. CONNELLY: He's entitled to ask for 09:55:39
21	MR. DAVIS: Object to the form.	21	something to be read back.
22	THE WITNESS: Yes.	22	THE WITNESS: Am I entitled to ask for it
23	BY MR. MURGATROYD:	23	to be read back?
24	Q. okay. And have you had a chance to go	24	MR. MURGATROYD: No. You're not. Not my
25	back and look at how many other variables that Paxil 09:54:16	25	question, because you've already answered it. 09:55:39
	Page 47		Page 49
1	failed to reach statistical significance on? 09:54:18	1	MS. CONNELLY: You know what, let's take a 09:55:39
2	A. No. I didn't go back and review anything	2	break if we're going to be argumentative and
3	last night other than doing the work to pull these.	3	abusive. It's not productive. We're on a
4	Q. Okay. But you're aware that there are	4	limited time here.
5	others that Paxil failed to reach statistical 09:54:28	5	MR. MURGATROYD: Fine. 09:55:39
6	significance on that were analyzed, but not included	6	MS. CONNELLY: Let's take a quick break
7	in your paper? Correct?	7	right now before you ask a question.
8	A. Yes.	8	MR. MURGATROYD: No. I don't care if --
9	Q. Okay. And so saying that it -- 4	9	MS. CONNELLY: I don't want to hear the --
10	passed -- Paxil passed statistical significance on 4 09:54:39	10	Counsel asks for a break. 09:55:39
11	out of 11 is actually an incorrect statement,	11	THE WITNESS: I would like a break.
12	because it was actually 4 out of a larger number?	12	MR. MURGATROYD: Go ahead and take a
13	Correct?	13	break.
14	MR. DAVIS: Object to the form;	14	VIDEOGRAPHER: At this time we're going
15	mischaracterizes the data. 09:54:50	15	off the record. The time is 9:57 a.m. 09:55:52
16	THE WITNESS: I don't think there's -- I	16	(Recess taken.)
17	don't think that -- let's see -- you were the	17	VIDEOGRAPHER: We're no back on the
18	one that asked about the 4 out of 11 so what's	18	record. The time is approximately 10:07 a.m.
19	your question?	19	Please proceed.
20	BY MR. MURGATROYD: 09:55:03	20	BY MR. MURGATROYD: 10:05:43
21	Q. There was actually more than 11?	21	Q. Before we took a break, Doctor, we were
22	MS. CONNELLY: I have to object to the	22	talking about the number of efficacy variables that
23	form. In the other questions you were pointing	23	were left out of your paper, correct?
24	to the paper and said, how many are there in	24	MR. DAVIS: Object to the form.
25	the paper -- 09:55:11	25	THE WITNESS: Yes. 10:06:13

Page 50	Page 52
1 BY MR. MURGATROYD: 10:06:13	1 MS. CONNELLY: Do you want the witness to 10:08:03
2 Q. And do you know what the total number is 3 that were left out of your paper that failed to 4 reach statistical significance in favor of Paxil?	2 review this document or just the table?
5 MR. DAVIS: Object to the form; it's been 10:06:22 6 asked and answered.	3 MR. MURGATROYD: Just the table.
7 THE WITNESS: No.	4 BY MR. MURGATROYD:
8 BY MR. MURGATROYD:	5 Q. Do you see that Table 22 on page 74 of 10:08:09
9 Q. Okay. Now, yesterday we did talk about 10 Dr. Stober asking that four efficacy variables be 10:06:26	6 that report, sir?
11 added and analyzed, correct? Do you recall that?	7 A. 22, page 74. Yes, I do.
12 A. I recall that.	8 Q. And does it discuss an analysis of the
13 MR. DAVIS: Objection to form.	9 four efficacy variables that we just discussed?
14 BY MR. MURGATROYD:	10 A. Yes, it does. 10:08:24
15 Q. And let me show you Exhibit 13 again. 10:06:31	11 Q. And can you determine from those tables
16 MR. DAVIS: And just so the record's 17 clear, added and analyzed for the study, not 18 added and analyzed for the paper because that	12 whether or not the four efficacy variables proposed
19 mischaracterizes what that document says.	13 by Mr. Stober reached statistical significance in
20 MR. MURGATROYD: I said added and analyzed 10:06:44	14 favor of Paxil?
21 for the study. I didn't say for the paper.	15 A. It's Dr. Strober. He's a Ph.D. 10:08:44
22 MR. DAVIS: Just so it's clear.	16 It looks like in observed cases the first
23 BY MR. MURGATROYD:	17 one reaches significance. Not in the last
24 Q. Do you see that? We talked about four --	18 observation carried forward, so that's
25 A. Yes. 10:06:58	19 anxiety/somatization reaches it in one of the two
Page 51	20 analysis. 10:08:59
1 Q. The first four? 10:06:59	21 Q. The one I'm concerned about is, last
2 A. Yes.	22 observation carried forward.
3 Q. And what are those four again.	23 A. I'm sorry. I thought you asked -- tell me
4 A. "Analyze HAM-D results using its four	24 the question you asked before.
5 factors." 10:07:03	25 Q. How many of the four variables proposed by 10:09:07
6 Q. Okay.	Page 53
7 A. So subscales of the HAM-D. The	1 Dr. Strober reached statistical significance in 10:09:13
8 anxiety/somatization.	2 favor of Paxil --
9 Q. Right.	3 A. Right. I was answering that question --
10 A. Sleep, cognitive disturbance and 10:07:03	4 Q. -- in regard to last observation carried
11 psychomotor slowing.	5 forward? 10:09:22
12 (Ryan Deposition Exhibit No. 50	6 A. That's a different question.
13 was marked for identification.)	7 Q. I understand.
14 Q. Okay. And now let me show you what I've	8 A. Okay. None of the four.
15 marked as Exhibit 50, which is the Final Clinical 10:07:20	9 Q. Okay. Now, whose decision was it to not
16 Report in its entirety with the exception of its	10 put the results of Dr. Strober's variables in your 10:09:29
17 appendices, and I want to turn your attention to	11 paper?
18 Table 22, which is found on page 74 of the report.	12 A. I can't imagine that you would have put it
19 MS. CONNELLY: Plaintiffs Exhibit 50 is a	13 in the paper. I don't know that it was discussed.
20 GSK produced document. It looks like it's 10:07:52	14 The issue, of course, is that for a secondary
21 subject to the protective order.	15 analysis and for exploration you look at a zillion 10:09:44
	16 things. This would have been very reasonable for
	17 secondary analyses. That's what our group was
	18 talking about with considerable enthusiasm at the
	19 time. So it -- it -- I certainly can't make nothing
	20 out of the fact that I don't remember this one being 10:10:05
	21 discussed and it wasn't put in the paper. It
	22 wouldn't have belonged in the paper.
	23 Q. I'm sorry. My question was: If you know
	24 who decided not to put it in the paper?
	25

<p style="text-align: right;">Page 54</p> <p>1 MR. DAVIS: Object to the form. 10:10:16</p> <p>2 BY THE WITNESS:</p> <p>3 Q. The results of those four --</p> <p>4 A. Right.</p> <p>5 Q. -- variables? 10:10:18</p> <p>6 A. Right. I do not know that this analysis</p> <p>7 was done by the time that the paper was written. I</p> <p>8 do not know that this analysis was ever presented to</p> <p>9 the investigators by the time the paper was written,</p> <p>10 and had it been done so it would have made little 10:10:28</p> <p>11 sense in this paper because it really is a secondary</p> <p>12 examination of a fine -- a minute question rather</p> <p>13 than the primary hypothesis of this one main study.</p> <p>14 Q. Well, let's see. We established yesterday</p> <p>15 that Jim McCafferty asked in August of 1997, a 10:10:39</p> <p>16 couple months before the blind was broken, to add an</p> <p>17 efficacy variable, correct? Do you recall that?</p> <p>18 A. Why don't you go back, because -- just go</p> <p>19 back and show me which one you're talking about, the</p> <p>20 efficacy variable, please? 10:10:58</p> <p>21 Q. Well, I'm not going to have enough time to</p> <p>22 do that today. You don't recall that from</p> <p>23 yesterday?</p> <p>24 MR. DAVIS: Object to the form.</p> <p>25 BY MR. MURGATROYD: 10:11:05</p>	<p style="text-align: right;">Page 56</p> <p>1 as -- I do not know the answer to your 10:11:59</p> <p>2 question. I do not think these were efficacy</p> <p>3 variables that he was proposing as primary</p> <p>4 analyses.</p> <p>5 BY MR. MURGATROYD: 10:12:13</p> <p>6 Q. They were analyzed? You agree with that,</p> <p>7 right?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. They were in the report?</p> <p>10 A. Yes. 10:12:14</p> <p>11 Q. And that report was prepared before your</p> <p>12 paper? Look at the report. What's the date of the</p> <p>13 report?</p> <p>14 MS. CONNELLY: You haven't asked a</p> <p>15 question yet. 10:12:24</p> <p>16 BY MR. MURGATROYD:</p> <p>17 Q. Okay. What's the date of the report?</p> <p>18 A. The date of the report is 24 November '98.</p> <p>19 Q. Three years before your paper was</p> <p>20 published? Correct? 10:12:39</p> <p>21 A. Yes.</p> <p>22 Q. Now, would you agree that is three more</p> <p>23 efficacy variables that were not included in your</p> <p>24 paper?</p> <p>25 MR. DAVIS: Object to the form. 10:12:52</p>
<p style="text-align: right;">Page 55</p> <p>1 Q. Do you recall Jim McCafferty writing to 10:11:05</p> <p>2 Rosemary Oakes saying, "Hey, I would like to analyze</p> <p>3 another efficacy variable"?</p> <p>4 MR. DAVIS: Object to the form.</p> <p>5 THE WITNESS: I need you to show me the 10:11:18</p> <p>6 form if you want to discuss it, because I can't</p> <p>7 entirely count on your representation of</p> <p>8 things.</p> <p>9 BY MR. MURGATROYD:</p> <p>10 Q. I'm just asking you if you recall it? 10:11:24</p> <p>11 A. I answered your question, sir.</p> <p>12 Q. Okay. You don't recall it? Correct?</p> <p>13 A. That's not my answer.</p> <p>14 Q. All right. Fine.</p> <p>15 A. My answer is show me and then I'll see if 10:11:26</p> <p>16 we're on agreement of your characterization of it.</p> <p>17 Q. Now, including Dr. Strober's four efficacy</p> <p>18 variables he asked to be analyzed, right, all of</p> <p>19 which failed to reach statistical significance using</p> <p>20 the last observation carried forward analysis, how 10:11:44</p> <p>21 many efficacy variables that were analysed were not</p> <p>22 included in your paper in addition to the 11 we've</p> <p>23 already talked about?</p> <p>24 MS. CONNELLY: Object to form.</p> <p>25 THE WITNESS: He was not proposing these 10:11:59</p>	<p style="text-align: right;">Page 57</p> <p>1 THE WITNESS: Yes. 10:12:52</p> <p>2 BY MR. MURGATROYD:</p> <p>3 Q. Okay. So now we have a total of 15?</p> <p>4 Correct?</p> <p>5 MS. CONNELLY: Object to form. A total of 10:13:01</p> <p>6 15 that were not included in a paper?</p> <p>7 MR. MURGATROYD: No. 15 efficacy</p> <p>8 variables that he's aware of? Right? We're</p> <p>9 trying to get to the number.</p> <p>10 MS. CONNELLY: I'm just trying to get a 10:13:05</p> <p>11 clear question.</p> <p>12 MR. MURGATROYD: I understand.</p> <p>13 BY MR. MURGATROYD:</p> <p>14 Q. Yesterday we established there was 11</p> <p>15 efficacy variables in the paper? Right? 10:13:09</p> <p>16 A. Yes.</p> <p>17 Q. And now we have an additional four?</p> <p>18 A. Your characterization of these as efficacy</p> <p>19 variables is dubious. Dr. Strober was -- you would</p> <p>20 not -- I -- in the treatment studies that I am 10:13:33</p> <p>21 familiar with using these compounds or similar</p> <p>22 compounds through the lifespans you would not count</p> <p>23 these as a primary or a secondary efficacy measure.</p> <p>24 you would look at these subsequently to say, did it</p> <p>25 specifically change that? So I think your 10:13:52</p>

Page 58	Page 60
<p>1 characterization of these four as efficacy variables 10:13:58</p> <p>2 is incorrect from the literature in psychiatry.</p> <p>3 Q. Well, does GSK analyze them as secondary</p> <p>4 variables?</p> <p>5 A. No. You said efficacy measures. As 10:14:13</p> <p>6 secondary variables, yes they're in analysis. As</p> <p>7 efficacy measures I don't think that</p> <p>8 characterization is completely correct.</p> <p>9 Q. I'm using the word -- if I said measures</p> <p>10 excuse me -- I meant to say variables. 10:14:28</p> <p>11 A. As efficacy variables? I don't think that</p> <p>12 characterizing these as efficacy variables for the</p> <p>13 treatment outcome is correct.</p> <p>14 Q. That's your opinion?</p> <p>15 A. I believe that's what I just expressed, 10:14:28</p> <p>16 sir.</p> <p>17 Q. Okay. All right. And Dr. Strober</p> <p>18 obviously asked that they be analyzed, correct?</p> <p>19 A. But not as outcome measures for the</p> <p>20 studies. 10:14:35</p> <p>21 Q. Okay. Do you know that for a fact?</p> <p>22 A. Let's see. What does it say? It is an</p> <p>23 expert informed opinion. I do not know it as a</p> <p>24 fact.</p> <p>25 Q. Thank you. Again, you were here today to 10:14:59</p>	<p>1 of my knowledge of the psychiatric literature 10:15:44</p> <p>2 and my knowledge of Dr. Strober.</p> <p>3 BY MR. MURGATROYD:</p> <p>4 Q. I'm going to move to strike your answer.</p> <p>5 Thank you, sir. 10:15:59</p> <p>6 I'm trying to get at the number of</p> <p>7 efficacy variables that you personally are aware of</p> <p>8 that failed to get into your paper and find out why</p> <p>9 they didn't get into your paper? Do you understand</p> <p>10 that? 10:16:14</p> <p>11 A. Yes.</p> <p>12 Q. We have determined that there are efficacy</p> <p>13 variables in which Paxil failed to reach statistical</p> <p>14 significance that didn't make it into your paper?</p> <p>15 Correct? 10:16:28</p> <p>16 A. I don't know that we've determined that</p> <p>17 yet, sir.</p> <p>18 Q. Well, I think you've already testified</p> <p>19 that that's true.</p> <p>20 MS. CONNELLY: Object to form. I don't 10:16:28</p> <p>21 recall any such testimony.</p> <p>22 THE WITNESS: I'm not recalling such</p> <p>23 testimony.</p> <p>24 BY MR. MURGATROYD:</p> <p>25 Q. Okay. When you give lectures such as the 10:16:39</p>
Page 59	Page 61
<p>1 talk about what you know. If you don't know, 10:14:59</p> <p>2 please, don't testify to that.</p> <p>3 MS. CONNELLY: Counsel, that's an</p> <p>4 interesting comment considering you've shown</p> <p>5 him multiple documents of which he has no 10:15:11</p> <p>6 first-hand knowledge of attempting to get him</p> <p>7 to testify about whether or not such documents</p> <p>8 say certain things or are authentic. So I</p> <p>9 suggest it be a two-way street.</p> <p>10 MR. DAVIS: I join in that. 10:15:14</p> <p>11 MR. MURGATROYD: And I will move to strike</p> <p>12 your comments from the record.</p> <p>13 BY MR. MURGATROYD:</p> <p>14 Q. And, Doctor, the purpose of this exercise</p> <p>15 is to try to determine how many efficacy variables 10:15:26</p> <p>16 were analyzed by GSK and not included in your paper?</p> <p>17 A. In my expert opinion these are not</p> <p>18 efficacy variables and Mike Strober did not intend</p> <p>19 them as that.</p> <p>20 Q. I'm sorry? You're testifying for Dr. 10:15:35</p> <p>21 Strober?</p> <p>22 MS. CONNELLY: He testified in his expert</p> <p>23 opinion.</p> <p>24 THE WITNESS: I'm giving you an expert</p> <p>25 opinion of what Dr. Strober intended, because 10:15:43</p>	<p>1 ones we've talked about, and we have a few more to 10:16:41</p> <p>2 go over, and you state in your slide presentation</p> <p>3 that Paxil is effective in treating adolescents with</p> <p>4 major depressive disorder, that is, in fact, you,</p> <p>5 stating to other physicians that it's okay to 10:17:01</p> <p>6 prescribe the drug to kids? Would you agree with</p> <p>7 that?</p> <p>8 MR. DAVIS: Object to the form.</p> <p>9 THE WITNESS: No, I would not.</p> <p>10 BY MR. MURGATROYD: 10:17:14</p> <p>11 Q. Would you agree that your colleagues who</p> <p>12 are listening to you and watching your slide</p> <p>13 presentation have the right to rely upon the</p> <p>14 accuracy of your information?</p> <p>15 MS. CONNELLY: Object to form. He can't 10:17:31</p> <p>16 testify for his colleagues according to your</p> <p>17 recent instruction.</p> <p>18 MR. DAVIS: I join in that objection.</p> <p>19 BY MR. MURGATROYD:</p> <p>20 Q. You can answer. 10:17:33</p> <p>21 A. Okay. Repeat the question, please.</p> <p>22 Q. Do you agree that your colleagues who</p> <p>23 listen to what you have to say and watch your slide</p> <p>24 presentation have the right to rely on the accuracy</p> <p>25 of your information? 10:17:58</p>

<p style="text-align: right;">Page 62</p> <p>1 MS. CONNELLY: Same objection. 10:17:58</p> <p>2 MR. DAVIS: Joined.</p> <p>3 THE WITNESS: I agree that my colleagues</p> <p>4 have a right to rely that I've done my best to</p> <p>5 present the data, the important data as it was 10:18:11</p> <p>6 known at the time, yes.</p> <p>7 (Ryan Deposition Exhibit No. 51</p> <p>8 was marked for identification.)</p> <p>9 BY MR. MURGATROYD:</p> <p>10 Q. If you would, please take a look at that 10:18:16</p> <p>11 document.</p> <p>12 A. Okay.</p> <p>13 Q. Can you identify for the record what this</p> <p>14 document is, sir?</p> <p>15 A. Yes. This was a talk I gave at the 10:18:37</p> <p>16 American College of Psychoneuropharmacology also</p> <p>17 known as the ACNP in December of 2001.</p> <p>18 Q. This is basically the same talk you gave a</p> <p>19 year earlier?</p> <p>20 A. No. 10:18:50</p> <p>21 Q. Okay. And in it do you include the slide</p> <p>22 that says Paxil is an effective treatment for MDD in</p> <p>23 adolescent outpatients?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. Let's go to the next exhibit. 10:19:13</p>	<p style="text-align: right;">Page 64</p> <p>1 A. Yes. 10:20:16</p> <p>2 Q. Okay. And in this -- well, why don't you</p> <p>3 tell us about this one? Who was this presented to?</p> <p>4 A. Sure. This was the one that we discussed</p> <p>5 briefly yesterday. This was presented at the 10:20:18</p> <p>6 American Psychiatric Association on May 2002 at an</p> <p>7 industry sponsored symposia sponsored by SKB or GSK.</p> <p>8 Q. Okay. And so were there representatives</p> <p>9 from GSK present at that meeting?</p> <p>10 A. I assume so. I didn't see them, any at 10:20:39</p> <p>11 the meeting, but it seems likely.</p> <p>12 Q. Okay. Because it was put on by them,</p> <p>13 right?</p> <p>14 A. Yes.</p> <p>15 Q. And in this presentation you talk about 10:20:50</p> <p>16 the side effects of Paxil?</p> <p>17 A. Yes.</p> <p>18 Q. In adolescents, right?</p> <p>19 A. Huh-huh.</p> <p>20 Q. Did you tell the audience about the number 10:21:09</p> <p>21 of suicide events that occurred during the clinical</p> <p>22 trial?</p> <p>23 MR. DAVIS: Object to the form.</p> <p>24 THE WITNESS: I do not have a slide on</p> <p>25 that. I believe something came up on that in 10:21:20</p>
<p style="text-align: right;">Page 63</p> <p>1 MR. DAVIS: 50 was the e-mail from Dr. 10:19:16</p> <p>2 Strober, is that right?</p> <p>3 MR. MURGATROYD: No. The e-mail from Dr.</p> <p>4 Strober was 13.</p> <p>5 MR. DAVIS: What is Exhibit 50? 10:19:16</p> <p>6 MR. MURGATROYD: 50 is the Clinical</p> <p>7 Report. The full version.</p> <p>8 MS. CONNELLY: Right. 1998, November 24.</p> <p>9 MR. DAVIS: Oh, for study?</p> <p>10 MS. CONNELLY: Final Clinical Report on 10:19:16</p> <p>11 329.</p> <p>12 MR. DAVIS: Thank you, ma'am.</p> <p>13 (Ryan Deposition Exhibit No. 52</p> <p>14 was marked for identification.)</p> <p>15 BY MR. MURGATROYD: 10:20:01</p> <p>16 Q. Okay. Let's go to what we've marked as</p> <p>17 Exhibit -- what number is that again?</p> <p>18 A. 52.</p> <p>19 Q. Great. And did you prepare this?</p> <p>20 A. Yes. 10:20:03</p> <p>21 Q. Is it authentic?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And you agree that all the</p> <p>24 information that you've provided today has been</p> <p>25 authentic, right, regarding these presentations? 10:20:14</p>	<p style="text-align: right;">Page 65</p> <p>1 the discussion. I'm not certain. I told them 10:21:20</p> <p>2 only about the ones that had a statistically</p> <p>3 significant difference, and in the study there</p> <p>4 was no statistically significant difference on</p> <p>5 the suicidality. 10:21:33</p> <p>6 BY MR. MURGATROYD:</p> <p>7 Q. Actually, there was ultimately?</p> <p>8 A. That's incorrect.</p> <p>9 Q. Okay.</p> <p>10 A. That's absolutely incorrect. 10:21:41</p> <p>11 Q. After the complete analyses of study 329?</p> <p>12 A. There's no analyses that I'm aware of</p> <p>13 where this study alone had a difference in the</p> <p>14 suicide rate. I'm sorry. I am aware of no such</p> <p>15 data, and certainly in all the data that I have seen 10:21:48</p> <p>16 there was no significant difference in the two.</p> <p>17 Q. And that was not a concern that you</p> <p>18 expressed along with Martin Keller when GSK told you</p> <p>19 about a manuscript they were going to publish about</p> <p>20 MMD? 10:22:13</p> <p>21 MR. DAVIS: Object to form.</p> <p>22 MS. CONNELLY: Object to form.</p> <p>23 BY MR. MURGATROYD:</p> <p>24 Q. Pediatric MDD? Do you know what I'm</p> <p>25 talking about? 10:22:22</p>

<p style="text-align: right;">Page 66</p> <p>1 A. No, I don't. 10:22:22</p> <p>2 MS. CONNELLY: That was vague.</p> <p>3 BY MR. MURGATROYD:</p> <p>4 Q. Okay. Well, let's take a look at that.</p> <p>5 Before we get into that -- and we'll get into that 10:22:26</p> <p>6 in a second -- do you agree that it was important in</p> <p>7 your presentation to inform the people present about</p> <p>8 the significant side effects that came up in your</p> <p>9 study?</p> <p>10 A. Yes. I informed them of the significant 10:22:39</p> <p>11 side effects. I was trying to do what I thought was</p> <p>12 best there. On this one, like every presentation</p> <p>13 I've ever made, I prepared the slides. I decided</p> <p>14 what to put in and out. There was, to the best of</p> <p>15 my knowledge, no vetting by GSK on this. 10:22:41</p> <p>16 Q. All right.</p> <p>17 VIDEOGRAPHER: Mr. Murgatroyd, we have two</p> <p>18 minutes.</p> <p>19 MR. MURGATROYD: Okay. Let's switch them</p> <p>20 out. 10:23:20</p> <p>21 VIDEOGRAPHER: At this time we're going</p> <p>22 off the record to change tapes. The time is</p> <p>23 10:24 a.m. This is the end of Tape 1.</p> <p>24 (Pause in Proceedings.)</p> <p>25 VIDEOGRAPHER: We are now back on the 10:26:11</p>	<p style="text-align: right;">Page 68</p> <p>1 I don't recall. 10:27:14</p> <p>2 BY MR. MURGATROYD:</p> <p>3 Q. All right. Well, let's take a -- well,</p> <p>4 first of all let's -- let me mark this exhibit.</p> <p>5 (Ryan Deposition Exhibit No. 53 10:28:05</p> <p>6 was marked for identification.)</p> <p>7 MR. DAVIS: Can I see it before it goes to</p> <p>8 the witness?</p> <p>9 MS. CONNELLY: Exhibit 53 is an</p> <p>10 unbates-stamped document. It appears to be 10:28:13</p> <p>11 from Dr. Keller.</p> <p>12 BY MR. MURGATROYD:</p> <p>13 Q. I'm going to show you a series of e-mails</p> <p>14 that we can have you read and then we can discuss</p> <p>15 them all at one time. 10:28:33</p> <p>16 A. Okay.</p> <p>17 VIDEOGRAPHER: At this time we're going</p> <p>18 off the record. The time is 10:31 a.m.</p> <p>19 (Recess taken.)</p> <p>20 VIDEOGRAPHER: We are now back on the 10:42:20</p> <p>21 record. The time is approximately 10:43 a.m.</p> <p>22 (Ryan Deposition Exhibit No. 54,</p> <p>23 55, 56, 57, was marked for identification.)</p> <p>24 BY MR. MURGATROYD:</p> <p>25 Q. Doctor, while we were all off the record I 10:42:29</p>
<p style="text-align: right;">Page 67</p> <p>1 record. This is the beginning of Tape Number 2 10:26:13</p> <p>2 of Dr. Neal Ryan. The time is 10:27 a.m.</p> <p>3 Please proceed.</p> <p>4 BY MR. MURGATROYD:</p> <p>5 Q. Doctor, before we took the break I asked 10:26:24</p> <p>6 you whether or not you were aware of a manuscript</p> <p>7 that GSK was proposing to publish entitled "Efficacy</p> <p>8 and Safety of Paroxetine for Pediatric MDD"? Do you</p> <p>9 recall that?</p> <p>10 MS. CONNELLY: Object to the form. You 10:26:48</p> <p>11 didn't ask that question before the break.</p> <p>12 MR. MURGATROYD: That's fine. Make your</p> <p>13 objection. Let's go on.</p> <p>14 BY MR. MURGATROYD:</p> <p>15 Q. Doctor, are you aware of a manuscript that 10:26:50</p> <p>16 GSK proposed to publish entitled "Efficacy and</p> <p>17 Safety of Paroxetine for Pediatric MDD"?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And do you recall that you and Dr.</p> <p>20 Keller were dismayed about that article being 10:26:58</p> <p>21 published?</p> <p>22 MR. DAVIS: Object to the form.</p> <p>23 THE WITNESS: I don't right now recall</p> <p>24 being dismayed to the extent that it was a</p> <p>25 duplication of what the FDA had done. Dismayed 10:27:11</p>	<p style="text-align: right;">Page 69</p> <p>1 showed you a number of exhibits; is that correct? 10:42:33</p> <p>2 A. Yes.</p> <p>3 Q. And what are the exhibit numbers?</p> <p>4 A. 53 through 57.</p> <p>5 Q. And did you get a chance to review those? 10:42:46</p> <p>6 A. Yes.</p> <p>7 Q. Do they help refresh your recollection as</p> <p>8 to the question I earlier asked you about being very</p> <p>9 dismayed about GSK publishing the MDD manuscript?</p> <p>10 MR. DAVIS: Object to the form. 10:43:03</p> <p>11 THE WITNESS: I now know what you were</p> <p>12 talking about, yes.</p> <p>13 BY MR. MURGATROYD:</p> <p>14 Q. And, in fact, those exact words were used</p> <p>15 in one of the e-mails by, I think, Dr. Keller that 10:43:01</p> <p>16 the group of you were very dismayed? Correct?</p> <p>17 A. Let's see. Dr. Keller used words like</p> <p>18 that. I think it was about a subissue and not about</p> <p>19 publication of the manuscript in general, however.</p> <p>20 I think it was one issue that he wanted to address 10:43:20</p> <p>21 and not the fact that the manuscript was to be</p> <p>22 published.</p> <p>23 Q. Well, what was the dismay that the group</p> <p>24 of you all had?</p> <p>25 A. Yes. Dr. Keller was the one who asserted 10:43:28</p>

Page 70	Page 72
<p>1 dismay for the group, and the issue was that in a 10:43:29</p> <p>2 reanalysis GSK had done in a paper aggregated the</p> <p>3 three depression treatment studies and looked at two</p> <p>4 things, one was efficacy and what they concluded in</p> <p>5 there was that none of the primary outcome measures 10:43:52</p> <p>6 came out significant in any of the three studies,</p> <p>7 but a meaningful number in the 329 Study of</p> <p>8 secondary measures indicated efficacy, and then they</p> <p>9 reported a reanalyses of the suicidal data.</p>	<p>1 I was also giving you a completely accurate 10:46:09</p> <p>2 answer that I certainly didn't remember at the</p> <p>3 time.</p> <p>4 BY MR. MURGATROYD:</p> <p>5 Q. Well, Table 10 is the discussion, the 10:46:18</p> <p>6 topic of discussion in the various e-mails that --</p> <p>7 well, let's make sure the record is clear: How many</p> <p>8 of those documents that I marked and you just</p> <p>9 reviewed came from your files?</p>
<p>10 In the reanalysis of that suicidal data on 10:44:13</p> <p>11 chart number 10 or Table 10 what they had is -- hold</p> <p>12 on a second -- that by reanalyses -- by</p> <p>13 reclassifying things they had significant P values</p> <p>14 in the 329 Study on several of the ways of looking</p> <p>15 at suicidality, specifically looking at things 10:44:35</p> <p>16 classified as self harm. Things classified as</p> <p>17 suicidal ideation and/or self harm -- I'm sorry --</p> <p>18 self harm during the on-therapy period, and then on</p> <p>19 the 30 days post-treatment period suicidal ideation</p> <p>20 and/or self harm or self harm considered alone. 10:44:50</p> <p>21 Q. And, Doctor -- I'm sorry.</p> <p>22 A. I'm sorry. Dr. Keller, what he was</p> <p>23 concerned about was that this appeared to be</p> <p>24 different -- this was different than what Dr.</p> <p>25 Keller, myself and others had published in the 10:45:09</p>	<p>10 A. I don't know. Certainly the document -- 10:46:35</p> <p>11 the Table 10 came from my files.</p> <p>12 Q. Okay.</p> <p>13 A. The other documents I do not know</p> <p>14 whether -- one of the documents came from my files,</p> <p>15 the others are not indicated. I did not review the 10:46:41</p> <p>16 stuff I gave you from my files.</p> <p>17 Q. Let's go through those documents one at a</p> <p>18 time. Pick one. Pick the earliest number.</p> <p>19 A. 53.</p> <p>20 Q. Okay. And can you please describe for the 10:46:59</p> <p>21 record what that document is?</p> <p>22 A. This is a printout of e-mail from -- the</p> <p>23 containing e-mail is from Dr. Keller to Dr.</p> <p>24 Carpenter, myself, Dr. Wagner, Dr. Emslie, Dr.</p> <p>25 Strober, Mr. Perera, Mr. Liptschiz, and it says, 10:47:14</p>
<p>Page 71</p> <p>1 original articles and in the letters and he wanted 10:45:11</p> <p>2 more explanation of why this was different than what</p> <p>3 we published before, because it was his assertion we</p> <p>4 acted in good faith with all data available to us,</p> <p>5 and so we wanted them to explain more clearly what 10:45:18</p> <p>6 the different methodology was that got these</p> <p>7 results.</p> <p>8 Q. Okay. And a minute ago I asked you if --</p> <p>9 and I think you testified, and correct me if I'm</p> <p>10 wrong, that you had never seen any document or any 10:45:28</p> <p>11 information that showed a -- that there was a</p> <p>12 significant -- statistically significant</p> <p>13 relationship of Paxil with suicidal ideation or</p> <p>14 suicide events? I think I used or suicidality ever?</p> <p>15 A. Did I say that there was none or did I say 10:45:48</p> <p>16 that I didn't remember it?</p> <p>17 Q. No. You said there was not. You said it</p> <p>18 didn't exist.</p> <p>19 MS. CONNELLY: I thought he said he hadn't</p> <p>20 seen it. 10:46:01</p> <p>21 THE WITNESS: I thought what I said was,</p> <p>22 to the best of my knowledge and that was the</p> <p>23 answer at that point.</p> <p>24 I completely agree that this paper was</p> <p>25 in my files so I had seen it at some point, but 10:46:07</p>	<p>Page 73</p> <p>1 "Please indicate where the points are in this 10:47:20</p> <p>2 paper", and then it contains a forward e-mail</p> <p>3 contained within it to basically the same</p> <p>4 individuals saying that he's concerned.</p> <p>5 Q. And that is an e-mail that you are carbon 10:47:35</p> <p>6 copied on?</p> <p>7 A. Yes.</p> <p>8 Q. Or you were ccd on?</p> <p>9 A. Yes.</p> <p>10 Q. And do you have any belief that you didn't 10:47:41</p> <p>11 ever receive it?</p> <p>12 A. No. I have no such belief.</p> <p>13 Q. Do you believe you did receive it?</p> <p>14 A. Yes.</p> <p>15 Q. And do you recall the discussions with Dr. 10:47:50</p> <p>16 Keller about the concern of the statistical</p> <p>17 significant P value for suicidality that was</p> <p>18 expressed in the paper?</p> <p>19 A. I recall them after looking at the paper.</p> <p>20 I did not before. 10:48:03</p> <p>21 Q. Okay. Let's go to the next document.</p> <p>22 MS. CONNELLY: I think -- I tried to put</p> <p>23 them in order.</p> <p>24 THE WITNESS: I'm sorry. I am probably</p> <p>25 helping you in the wrong way then. 10:48:11</p>

Page 74			Page 76		
1	BY MR. MURGATROYD:	10:48:11	1	I mean my understanding of what Dr. Keller is	10:50:18
2	Q. And before we go to the next one, the last		2	saying to us here is that the authors had a	
3	one, does that document appear to be authentic to		3	much stronger obligation to be clear about why	
4	you? The first Exhibit 53?		4	a subsequent analyses showed different results	
5	A. I have no way to authentic this one.	10:48:18	5	than what we published in good faith before.	10:50:24
6	Q. Okay. Do you have any reason to believe		6	Q. And that had to do with the suicide issue?	
7	it's not authentic?		7	A. That's correct.	
8	A. No.		8	Q. Okay. And the next document, please.	
9	Q. Okay. Let's take a look at the next one.		9	A. Exhibit 54. It's e-mail from Dr. Keller	
10	A. The one that we believe next is in	10:48:28	10	to myself, Mike Strober and Karen Wagner. It says:	10:50:41
11	chronological order is Plaintiffs Exhibit 57.		11	We're extremely concerned about major pieces of the	
12	E-mail from Martin Keller to myself, Mike Strober,		12	draft, differences reported there from the 329	
13	Karen Wagner and Graham Emslie. This one appears to		13	paper.	
14	be from my files. It says: David Carpenter and Alan		14	Q. And what were the differences that are	
15	Lipschitz just called me to say upper management was	10:48:28	15	expressed in this one?	10:50:59
16	told of our strong opinion that they write separate		16	A. It's again the question of what -- with	
17	papers and they -- management rejected it.		17	the lack of explanation on why that data on	
18	Q. Okay. And is that document authentic?		18	suicidality is different.	
19	A. It's from my files. I assume it's		19	Q. And the concern about the P value of the	
20	authentic. I can't further authentic it.	10:48:39	20	suicide events?	10:51:11
21	Q. Okay. It's from your files, correct?		21	A. Right. It's not that -- it says, "what	
22	A. By the notes here, yes.		22	accounts for the differences and how to explain	
23	Q. Okay. And do you recall receiving that?		23	this." Not the fact that they came out. There was	
24	A. I do not specifically recall receiving		24	nothing in here to indicate Dr. Keller was concerned	
25	this e-mail.	10:48:59	25	that there were P values. He was concerned that it	10:51:20
Page 75			Page 77		
1	Q. Okay. But you know that you did?	10:49:01	1	was a different analyses and they didn't explain why	10:51:24
2	A. Yes.		2	the different analyses.	
3	Q. Okay. Good. Let's go to the next one.		3	Q. Well, he was concerned about the P values	
4	A. The next one is 56. The covering e-mail		4	too, correct?	
5	and manuscript, the draft manuscript. It's from	10:49:11	5	MR; DAVIS: Object to form.	10:51:29
6	David Carpenter to Martin Keller, Graham Emslie,		6	MS. CONNELLY: Objection to the form.	
7	Karen Wagner, Mike Strober, myself. This one's also		7	BY MR. MURGATROYD:	
8	from my files.		8	Q. That's referenced in the documents I just	
9	Q. So that document's authentic?		9	gave you?	
10	A. To the best of my knowledge.	10:49:28	10	A. Okay. I don't think that characterization	10:51:33
11	Q. And the next one, please?		11	is at all correct.	
12	A. The next one is dated 6-13-04. It says		12	Q. Okay. Let me see the documents. Let me	
13	from Marty Keller to Ryan, Strober and Wagner,		13	show you Exhibit 54, and I'm reading into the record	
14	partial draft respond and it talks about		14	under one and then I'll have you take a look at it	
15	dissatisfaction with the paper.	10:49:46	15	to make sure I did this correctly.	10:52:01
16	Q. And that had to do with regard to Table 10		16	It states "No where before (329 paper or	
17	and the P values that showed a statistical		17	responses to Jetter). Who is Jetter?	
18	significant relationship between Paxil and		18	A. It was one of the letters to the editor	
19	suicidality idealization and/or self harm?		19	that we responded to in the subsequent.	
20	MR. DAVIS: Objection to form.	10:50:03	20	Q. Well, actually, Jetter's a reporter with	10:52:24
21	THE WITNESS: I think that's close, but		21	Health Magazine, isn't she?	
22	not correct. What it had to do with is the		22	A. You're right. I was wrong.	
23	fact that the paper didn't describe by this		23	Q. And it says, "No where before (329 paper	
24	analysis why it came out different, and so my		24	for responses to Jetter) did we report any of the 3	
25	understanding of the reading of Dr. Keller's --	10:50:14	25	significant P values reported here."	10:52:39

Page 78	Page 80
<p>1 Now, just make sure I read that correctly. 10:52:39</p> <p>2 A. You read that correctly.</p> <p>3 Q. Okay. And what is that referring to?</p> <p>4 A. It's referring to the fact that this is a</p> <p>5 new analyses with P values on things that we had 10:52:52</p> <p>6 looked at before, and the best data we had before</p> <p>7 didn't have a significant P value there, and so the</p> <p>8 fact that you reanalyzed -- we analyzed</p> <p>9 statistically correctly before and didn't have a P</p> <p>10 value -- they had reclassified people and 10:53:09</p> <p>11 reclassified and did have a P value, but they didn't</p> <p>12 explain the reclassification.</p> <p>13 Q. And you were told -- do you remember being</p> <p>14 told at some point in time that there were more</p> <p>15 suicide events in your study than you had originally 10:53:24</p> <p>16 reported? Do you recall getting those e-mails from</p> <p>17 GSK?</p> <p>18 A. I'm not recalling, but you can show me or</p> <p>19 I can take your word for it, but I'm not recalling</p> <p>20 it. 10:53:52</p> <p>21 Q. All right. Let's take a look at it.</p> <p>22 A. But that would be part and parcel of</p> <p>23 what's in here. I mean, the reanalyses finding more</p> <p>24 would certainly be consistent with what's in here,</p> <p>25 yes. 10:53:59</p>	<p>1 interpretation. 10:55:05</p> <p>2 Q. Well, let me ask yo this: Whose job was</p> <p>3 it to properly classify the adverse events? Was it</p> <p>4 the investigators or was it GSK's?</p> <p>5 MR. DAVIS: Object to form. 10:55:09</p> <p>6 THE WITNESS: It was GSK's job. That's</p> <p>7 why we broke it down. GSK classified the</p> <p>8 events. It would have been their job to</p> <p>9 classify them properly.</p> <p>10 (Ryan Deposition Exhibit No. 58 10:55:16</p> <p>11 was marked for identification.)</p> <p>12 BY MR. MURGATROYD:</p> <p>13 Q. Okay. That's fine. Now, let me show you</p> <p>14 the next document that I've marked as Exhibit 58,</p> <p>15 and let me show you another document. 10:55:28</p> <p>16 MS. CONNELLY: Exhibit 58 is one of Dr.</p> <p>17 Ryan's documents, but it's been marked with</p> <p>18 highlighting. Is this your highlighting?</p> <p>19 MR. MURGATROYD: Oh, it may be. Here.</p> <p>20 Let's swap it out. Here. 10:55:37</p> <p>21 MS. CONNELLY: It doesn't matter.</p> <p>22 MR. MURGATROYD: No. It doesn't make any</p> <p>23 difference. It's my highlighting.</p> <p>24 MS. CONNELLY: Just so you know that</p> <p>25 Counsel has highlighted that. 10:55:37</p>
<p>Page 79</p> <p>1 Q. Well, it isn't that new patients all of a 10:53:59</p> <p>2 sudden appeared and had adverse events? These were</p> <p>3 adverse events that the patients had during the</p> <p>4 clinical trial? Right?</p> <p>5 A. Yes. They were adverse events when they 10:54:13</p> <p>6 were reclassified -- were being related to</p> <p>7 suicidality that were not so classified in the first</p> <p>8 place, yes, that's my understanding.</p> <p>9 Q. And who made that error? Was that the</p> <p>10 investigator or GSK? 10:54:22</p> <p>11 MR. DAVIS: Objection to the form; no</p> <p>12 foundation.</p> <p>13 THE WITNESS: Yes. I think I would have</p> <p>14 no data -- let's see, error is not, I think,</p> <p>15 the correct way of classifying that. I think 10:54:29</p> <p>16 they did a good job of classifying it first to</p> <p>17 the best of knowledge and then they did more</p> <p>18 complete, more elaborate ways and it came out</p> <p>19 slightly different.</p> <p>20 BY MR. MURGATROYD: 10:54:44</p> <p>21 Q. Well, they were the same events? I mean,</p> <p>22 the events didn't change, right?</p> <p>23 A. As we talked about yesterday it was vague</p> <p>24 in many cases, text descriptions of what happened,</p> <p>25 the classification of the events were open to 10:54:59</p>	<p>Page 81</p> <p>1 MR. DAVIS: May I see that? 10:55:46</p> <p>2 (Ryan Deposition Exhibit No. 59</p> <p>3 was marked for identification.)</p> <p>4 BY MR. MURGATROYD:</p> <p>5 Q. And let me show you what I'm marking as 10:55:48</p> <p>6 Exhibit 59 to go along with it.</p> <p>7 A. Okay.</p> <p>8 Q. Okay. Now, these are Exhibits 58 and 59,</p> <p>9 correct?</p> <p>10 A. That's correct. 10:56:50</p> <p>11 Q. And they both came from your files,</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. Both documents are authentic?</p> <p>15 A. To the best of my knowledge. 10:56:59</p> <p>16 Q. Okay. And both of these are e-mails from</p> <p>17 you, right?</p> <p>18 A. That's correct.</p> <p>19 Q. So you prepared these?</p> <p>20 A. Yes. 10:57:11</p> <p>21 Q. And let's take 59 first.</p> <p>22 A. Okay.</p> <p>23 Q. 59. Can you please tell the jury what 59</p> <p>24 is.</p> <p>25 A. 59 is e-mail from me to Philip and Erica 10:57:16</p>

<p style="text-align: right;">Page 82</p> <p>1 Wetherhold containing e-mail from me to David 10:57:22</p> <p>2 Carpenter, Jim McCafferty, Regan Fong, Philip</p> <p>3 Perera, Alan Lipschitz and ccd to Drs. Keller,</p> <p>4 Strober and Wagner entitled, "Study 329 update"</p> <p>5 referring to e-mail from the prior day from Regan 10:57:33</p> <p>6 Fong to Drs. Keller, Wagner and myself with ccs to</p> <p>7 the GSK people saying, "With your e-mail (appended</p> <p>8 below) about 4 additional 'events' in Study 329 on</p> <p>9 the Paxil arm, those of us involved in writing the</p> <p>10 recent letter to the reporter asking about details 10:57:59</p> <p>11 of our article need very very quickly to get</p> <p>12 absolutely as much information as you have and</p> <p>13 understand what part of this we need to pass on to</p> <p>14 her. Otherwise we are in the challenging position</p> <p>15 of sending her a good-faith effort at directly 10:58:09</p> <p>16 answering her questions that we find very shortly</p> <p>17 thereafter is no longer the most complete</p> <p>18 information available to us and which therefore</p> <p>19 might appear misleading. Can we get a much fuller</p> <p>20 explantation in e-mail? Should we quickly set up a 10:58:18</p> <p>21 conference phone call?"</p> <p>22 The last containing one is the update.</p> <p>23 This is again from GSK, but it doesn't say who it</p> <p>24 was from on here -- I'm sorry -- from Regan Kong.</p> <p>25 Says, "Dear all, we want to update you, as 10:58:33</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. Okay. And you responded and told her that 10:59:50</p> <p>2 none of the suicide events didn't reach statistical</p> <p>3 significance? Right?</p> <p>4 MR. DAVIS: Object to form.</p> <p>5 THE WITNESS: I didn't respond, but Dr. 11:00:05</p> <p>6 Keller did. I don't remember that e-mail</p> <p>7 correspondence, but it's likely that we would</p> <p>8 have done such, because by the best data they</p> <p>9 had they did not.</p> <p>10 BY MR. MURGATROYD: 11:00:09</p> <p>11 Q. And this e-mail talks about your problem</p> <p>12 with that? Right?</p> <p>13 A. Yes. That we have to get her better</p> <p>14 information once we know it. Absolutely and</p> <p>15 Q. Okay. 11:00:16</p> <p>16 A. -- because there were P values that --</p> <p>17 Q. Right.</p> <p>18 A. -- that GSK had reclassified things from</p> <p>19 the process we had talked about before, and there</p> <p>20 were 4 more which would change the information we 11:00:18</p> <p>21 were giving her and we didn't want to give her</p> <p>22 incorrect information.</p> <p>23 Q. Okay. And did you go back and correct the</p> <p>24 information?</p> <p>25 A. I was never the one corresponding with 11:00:24</p>
<p style="text-align: right;">Page 83</p> <p>1 investigators on Study 329, about additional 10:58:35</p> <p>2 potential pediatric suicidality cases that were</p> <p>3 recently discovered. In a manual review of all SAE</p> <p>4 narratives and 'trauma' cases, 10 additional events</p> <p>5 potentially suggestive of intentional self injury, 10:58:41</p> <p>6 suicidal ideation, or suicide attempt were</p> <p>7 identified. Four of the 10 events occurred in Study</p> <p>8 329, all in the paroxetine group. Consequently,</p> <p>9 this could potentially change the number of</p> <p>10 paroxetine suicide-related adverse events for the 10:59:03</p> <p>11 study from 6 to 10. These cases are included among</p> <p>12 those undergoing blinded review by Dr. Wagner, Dr.</p> <p>13 Ryan, and Dr. Apter for the pediatric suicidality</p> <p>14 manuscript. Please feel free to contact us if you</p> <p>15 have any questions." 10:59:16</p> <p>16 Q. Okay. Ms. Jetter with Health Magazine had</p> <p>17 actually sent a series of questions that you and</p> <p>18 your group responded to?</p> <p>19 A. Yes. Dr. Keller took the lead in that,</p> <p>20 but yes she had. 10:59:28</p> <p>21 Q. And one of the things she asks about are</p> <p>22 the suicide events that occurred in Study 329?</p> <p>23 Correct?</p> <p>24 A. That would reflect both this document and</p> <p>25 my memory, yes. 10:59:50</p>	<p style="text-align: right;">Page 85</p> <p>1 her. I assume that Dr. Keller did. My memory is 11:00:28</p> <p>2 not sufficient to guarantee that he did.</p> <p>3 Q. Now, in Exhibit 58, can you read the</p> <p>4 second paragraph in the record?</p> <p>5 A. Sure. 11:00:41</p> <p>6 Q. Just the first two sentences.</p> <p>7 A. "FDA made each company go line by line</p> <p>8 through absolutely all documentation of all kids in</p> <p>9 all their studies. This is where 4 more subjects in</p> <p>10 our joint study fell out, unfortunately, all in the 11:00:50</p> <p>11 Paxil group."</p> <p>12 This is an e-mail from me to Drs. Keller,</p> <p>13 Strober and Wagner and dated --</p> <p>14 Q. That's fine. And my question was: Why</p> <p>15 was it unfortunate that they were all in the Paxil 11:01:05</p> <p>16 group?</p> <p>17 A. Yes. Because then it meant that what we</p> <p>18 published in the paper was -- you know, if they come</p> <p>19 out in both cells then we simply have additional</p> <p>20 information that doesn't change the paper. If it 11:01:16</p> <p>21 comes out in one cell then we've got to go back and</p> <p>22 correct things, because we have more data.</p> <p>23 Q. Okay. Did you go back and correct your</p> <p>24 paper?</p> <p>25 A. GSK was getting the data out there so 11:01:26</p>

<p style="text-align: right;">Page 86</p> <p>1 there was no erratum to the paper. This was a 11:01:28</p> <p>2 subsequent analyses.</p> <p>3 Q. Okay. That's fine. So no erratum to your</p> <p>4 paper has been done to your knowledge?</p> <p>5 A. To my knowledge, no. 11:01:41</p> <p>6 Q. Okay.</p> <p>7 A. That also wouldn't be the way you would</p> <p>8 handle a secondary analyses. That is the way you</p> <p>9 handle an error in the first one or something.</p> <p>10 Q. Okay. Now, yesterday we talked about, and 11:01:48</p> <p>11 actually we have ...</p> <p>12 MS. CONNELLY: Just for timing issues,</p> <p>13 it's a little after 11:00.</p> <p>14 MR. MURGATROYD: Okay.</p> <p>15 MS. CONNELLY: You had said you wanted to 11:02:20</p> <p>16 reserve an hour. Are you still going to do</p> <p>17 that or no?</p> <p>18 MR. MURGATROYD: I'm going to continue in</p> <p>19 this for probably another half hour and then</p> <p>20 I'll reserve a half hour. 11:02:33</p> <p>21 MS. CONNELLY: Okay.</p> <p>22 BY MR. MURGATROYD:</p> <p>23 Q. Do you remember yesterday when we talked</p> <p>24 about the document that said there was a 5.9</p> <p>25 percent -- the risk ratio of a suicide event of an 11:02:37</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. Well, I wanted to know whether or not you 11:03:48</p> <p>2 knew that there was a five-plus -- almost six-fold?</p> <p>3 A. That wasn't the question you asked me</p> <p>4 yesterday. Your implication on that question was I</p> <p>5 was being deliberately misleading. That's not an 11:04:03</p> <p>6 assertion I want to support. I was not being so.</p> <p>7 Q. Well, let's take a look at the next</p> <p>8 document I'm going to mark here.</p> <p>9 (Ryan Deposition Exhibit No. 60</p> <p>10 was marked for identification.) 02:47:32</p> <p>11 BY MR. MURGATROYD:</p> <p>12 Q. Okay. And can you identify for the record</p> <p>13 what that document is, sir?</p> <p>14 A. This appears to be an e-mail from myself</p> <p>15 to Drs. Keller, Strober, and Phil Perera at GSK. It 11:06:44</p> <p>16 says, "Please look at my draft answers. I hope I've</p> <p>17 got them right but you may have to tweak them since</p> <p>18 I don't know all the GSK internal stuff."</p> <p>19 Q. Okay. And that's an authentic document?</p> <p>20 A. It looks like it. 11:07:07</p> <p>21 Q. It came from your files, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Do you have any reason to think it's not</p> <p>24 authentic?</p> <p>25 A. No. 11:07:09</p>
<p style="text-align: right;">Page 87</p> <p>1 adolescent taking Paxil versus an adolescent taking 11:02:48</p> <p>2 placebo was 5.9? Do you remember us talking about</p> <p>3 that?</p> <p>4 A. I remember talking about the risk ratio.</p> <p>5 I remember that it was approximately, but not 11:02:59</p> <p>6 exactly 5.9.</p> <p>7 Q. Okay. And at some point you said, we'll</p> <p>8 get into whether or not that was the active drugs or</p> <p>9 the Paxil load?</p> <p>10 A. I'm sorry. Say that again, please? 11:03:09</p> <p>11 Q. I think, if I'm correct, you said, well,</p> <p>12 you didn't know because it said drug? Do you</p> <p>13 remember saying that?</p> <p>14 A. I said, by that table the table didn't</p> <p>15 indicate whether it was imipramine plus the Paxil or 11:03:16</p> <p>16 the Paxil group alone.</p> <p>17 MR. DAVIS: Object to form.</p> <p>18 BY MR. MURGATROYD:</p> <p>19 Q. Well, I mean, you would know that from</p> <p>20 your work on the case, right? 11:03:33</p> <p>21 A. I would have to review the original table</p> <p>22 on imipramine to see if that could have been the</p> <p>23 combined two. You presented me one page out of a</p> <p>24 middle of a big document and asked me to comment on</p> <p>25 one table on one page. 11:03:43</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. And you prepared it, right? 11:07:11</p> <p>2 A. Yes.</p> <p>3 Q. And does it refresh your recollection as</p> <p>4 to whether or not the 5.9 risk ratio of a Paxil</p> <p>5 patient versus a placebo patient existed with regard 11:07:16</p> <p>6 to just Paxil?</p> <p>7 A. Right. You're mischaracterizing my prior</p> <p>8 answer.</p> <p>9 Q. I'm just asking a question.</p> <p>10 A. Ask the question again, please. 11:07:33</p> <p>11 Q. Okay. Does that paper discuss a 5.9 risk</p> <p>12 ratio with regard to adolescents taking Paxil versus</p> <p>13 adolescents taking placebo?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Good. So the 5.9 risk ratio you 11:07:59</p> <p>16 would agree is not the combined imipramine and Paxil</p> <p>17 drugs, it's just Paxil?</p> <p>18 A. I have no knowledge of what the combined</p> <p>19 imipramine plus Paxil one is. 5.9 is certainly the</p> <p>20 number to represent Paxil. 11:08:13</p> <p>21 Q. Thank you, sir. Now, are you aware that</p> <p>22 study 329 was the reason the FDA looked into the</p> <p>23 issue of suicidality in kids taking antidepressants?</p> <p>24 MS. CONNELLY: Object to form; that</p> <p>25 assumes a fact that is not in evidence. 11:08:26</p>

Page 90	Page 92
1 THE WITNESS: That's actually not the case. 2 3 MR. DAVIS: Join. And we all did discuss 4 this yesterday.	1 7? 2 3 A. "This May 22, 2003 report suggested an 4 increased risk (paroxetine vs. placebo) of various 5 thoughts and behaviors coded as events considered 6 'possibly suicide related' and also for the subgroup 7 of these events that met the sponsor's criteria for 8 representing 'suicide attempts.' The signal for 9 increased risk was clearest for 1 of the 3 trials 10 involving pediatric patients with MDD. A summary of 11 the sponsor's finding for the MDD trials in the 12 Paxil program is included in Appendix 2.
5 BY MR. MURGATROYD: 6 Q. Well, let's take look at the next exhibit. 7 I think you said you've seen this document before. 8 MS. CONNELLY: Had it been previously 9 marked as an exhibit? 10 (Ryan Deposition ` No. 61 11 was marked for identification.)	11 11:12:31 12 13 Q. Okay. And so it talks about a signal, 14 correct? 15 A. That's correct.
12 MR. MURGATROYD: Yes. I think he 13 testified he had read it before. Right? I 14 have one section of the document -- obviously, 15 you're free to read the entire document. 16 MS. CONNELLY: Plaintiffs Exhibit 61 is a 17 memorandum from the Department of Health and 18 Human Services, FDA, on February 5, 2004, and 19 Counsel has directed the witness to page 7 of 20 the document. 21 BY MR. MURGATROYD: 22 Q. And, actually, let me direct you to one 23 other section too. Page 6. The bottom of page 6. 24 A. Okay.	16 17 18 Q. Appearing in one of the 3 MDD trials? 19 Right? 20 A. Yes. 21 Q. And you would agree that one is Study 329? 22 A. Yes. 23 Q. Thank you. And yesterday you testified 24 that you didn't think you had a signal regarding 25 suicidality in your trial? Right. 26 A. That's correct.
15 11:09:16 16 17 18 19 20 11:10:09 21 22 23 24 25 11:11:22	15 11:12:35 16 17 18 19 20 11:12:41 21 22 23 24 25 11:13:20
16 MS. CONNELLY: Plaintiffs Exhibit 61 is a 17 memorandum from the Department of Health and 18 Human Services, FDA, on February 5, 2004, and 19 Counsel has directed the witness to page 7 of 20 the document. 21 BY MR. MURGATROYD: 22 Q. And, actually, let me direct you to one 23 other section too. Page 6. The bottom of page 6. 24 A. Okay. 25 Q. Are you familiar with that document?	16 17 18 19 20 21 22 23 24 25
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Page 91	Page 93
1 A. I'm sorry? 2 Q. Are you familiar with that document? 3 A. I sorry. Say that again. 4 Q. Are you familiar with that document? 5 A. I almost -- I read -- I reviewed most of 6 the documents that were put on the FDA web site that 7 were related to this particular pediatric advisory 8 committee meeting at one time so almost certainly I 9 looked at this document. I'm not -- I didn't spend 10 much time on this particular one and obviously you 11 gave me a chance to review it this morning. 12 Q. Okay. And I asked you to look at the 13 bottom of Page 6; is that correct? 14 A. That's correct. 15 Q. And can you read that into the record, 16 please, sir? 17 A. "Origins of Present Concern About the 18 Emergence of Pediatric Suicidality in Association 19 with Antidepressant Use; Initial Regulatory 20 Response. Background to May 2003 Paroxetine 21 Report." 22 Q. Okay. And paroxetine is Paxil, right? 23 A. That's correct. 24 Q. And can you read into the record the 25 yellow -- the part I've marked at the bottom of Page	1 MR. DAVIS: Object to the form. 2 THE WITNESS: Let's see. The data that we 3 had did not suggest a signal and we reported 4 that accurately in the paper. The FDA talks 5 about the subsequent analyses that GSK did and 6 using that says that -- and said that there was 7 a signal. 8 BY MR. MURGATROYD: 9 Q. Now, that document that you have was a 10 preclude to a meeting that the FDA had in February 11 of 2004, correct? 12 A. Yes. 13 Q. And you wanted to be a participate in that 14 meeting, correct? 15 A. No. 16 Q. Well, weren't you on the -- didn't you 17 want to be part of the Advisory Committee? 18 A. No. I in the most way wanted to be 19 conflicted off, because I was fair and square 20 conflicted. I was delighted when they told me -- 21 the -- on that Advisory Committee which I was a 22 member of they can ask for a variance for a member 23 who has a conflict of interest. They do that 24 frequently. It was my great hope that they would do 25 that for me at that meeting. They decided I was in
11:11:24 11:11:29 11:11:50 11:12:01 11:12:03 11:12:22	11:13:20 11:13:35 11:13:50 11:14:07 11:14:20 11:14:29

<p style="text-align: right;">Page 94</p> <p>1 conflict. I was not there. That was a very good 11:14:31</p> <p>2 decision on their part and pleased me.</p> <p>3 Q. And so if --</p> <p>4 A. The last thing you want to do is appear to</p> <p>5 be impartial on a study you took part in. That 11:14:43</p> <p>6 would have been crazy.</p> <p>7 Q. Okay. So if David Carpenter testified</p> <p>8 that the reason you dropped out of the after-suicide</p> <p>9 manuscript was because you wanted to be on that</p> <p>10 committee that would have been an inaccurate 11:15:03</p> <p>11 statement by Dr. Carpenter?</p> <p>12 MS. CONNELLY: Object to form; again, it's</p> <p>13 based on a fact which is not in evidence in</p> <p>14 this case.</p> <p>15 MR. MURGATROYD: And now it is. There is. 11:15:13</p> <p>16 MS. CONNELLY: Then can you present to the</p> <p>17 witness the evidence upon which you're relying?</p> <p>18 MR. DAVIS: That mischaracterizes Dr.</p> <p>19 Carpenter's testimony.</p> <p>20 BY MR. MURGATROYD: 11:15:20</p> <p>21 Q. Okay. You can answer the question.</p> <p>22 A. I have no idea what was going on in Dr.</p> <p>23 Carpenter's mind. That would certainly not reflect</p> <p>24 anything that was going on in my mind. I definitely</p> <p>25 did not want to be there, and the reason for 11:15:28</p>	<p style="text-align: right;">Page 96</p> <p>1 your efforts. 11:16:13</p> <p>2 THE WITNESS: No. You did not say that.</p> <p>3 MS. CONNELLY: Yes, you did.</p> <p>4 MR. MURGATROYD: Well, let's make it very</p> <p>5 clear. 11:16:13</p> <p>6 THE WITNESS: Fine.</p> <p>7 BY MR. MURGATROYD:</p> <p>8 Q. Would you agree that the university was</p> <p>9 paid by GSK a large sum of money for your efforts</p> <p>10 having to do with Study 329? 11:16:24</p> <p>11 MR. DAVIS: Object to the form.</p> <p>12 THE WITNESS: For my efforts on 329 they</p> <p>13 were paid a considerably more modest sum of</p> <p>14 money. The total amount was about \$500,000 for</p> <p>15 their expenses in carrying out the studies, 11:16:43</p> <p>16 including a little bit of my salary over that</p> <p>17 interval.</p> <p>18 Q. And was --</p> <p>19 A. That was total expenses for doing that.</p> <p>20 For hiring the staff to do it. For all the costs 11:16:48</p> <p>21 associated with the study. Not for my effort alone.</p> <p>22 Q. Okay. So the information that I have from</p> <p>23 GSK is that they paid your university \$541,017.60,</p> <p>24 does that approximately?</p> <p>25 A. Yes. 11:17:03</p>
<p style="text-align: right;">Page 95</p> <p>1 dropping out of that one is that it was 11:15:31</p> <p>2 non-contributory.</p> <p>3 Q. And you agree that you through the</p> <p>4 University, for your efforts on 329, was paid a</p> <p>5 large sum of money? 11:15:43</p> <p>6 MR. DAVIS: Object to the form. We went</p> <p>7 over this yesterday.</p> <p>8 BY MR. MURGATROYD:</p> <p>9 Q. I'm sorry?</p> <p>10 A. I said no. 11:15:44</p> <p>11 Q. Well --</p> <p>12 A. Would you characterize a large sum in that</p> <p>13 I can you give you an answer to that more specific?</p> <p>14 Q. Well, over a half million dollars?</p> <p>15 MR. DAVIS: Object to the form. 11:15:59</p> <p>16 THE WITNESS: I'm sorry. Then that's</p> <p>17 dramatically false.</p> <p>18 BY MR. MURGATROYD:</p> <p>19 Q. So if I got an interrogatory response</p> <p>20 from -- 11:16:05</p> <p>21 A. You said that I was paid over a half</p> <p>22 million dollars?</p> <p>23 MS. CONNELLY: Yes, you did. Yes, you</p> <p>24 did.</p> <p>25 MR. MURGATROYD: I said the university for 11:16:13</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. Okay. And how much of that went into your 11:17:03</p> <p>2 pocket?</p> <p>3 MR. DAVIS: Object to the form.</p> <p>4 THE WITNESS: The best I can say -- I do</p> <p>5 not know what fraction of my salary was 11:17:13</p> <p>6 covered, but whatever fraction of my salary was</p> <p>7 covered was no additional money to me over my</p> <p>8 salary. So there was -- so part of that</p> <p>9 covered my salary versus something else</p> <p>10 covering my salary was financially immaterial 11:17:22</p> <p>11 to me.</p> <p>12 I was a tenured full professor at the</p> <p>13 time so the university had an obligation to pay</p> <p>14 me and I would have simply done different work;</p> <p>15 in addition, my best estimate was I would have 11:17:31</p> <p>16 gotten a bonus over that time of about \$7000</p> <p>17 and I would have gotten a bonus for doing</p> <p>18 different things had I done different things.</p> <p>19 So that's -- the most one could assert I got</p> <p>20 additional for this study was \$7000 to me, and 11:17:43</p> <p>21 realistically the number is probably zero.</p> <p>22 BY MR. MURGATROYD:</p> <p>23 Q. And are you aware that different entities</p> <p>24 have made assertions that you were paid by GSK to</p> <p>25 evaluate the data on Paxil and suicidality, the 11:18:05</p>

Page 98	Page 100
1 blinded review? 11:18:05	1 can take a look at the two combined. 11:20:03
2 MR. DAVIS: Object to form.	2 MS. CONNELLY: So we've got some web site
3 MS. CONNELLY: Object to form; again, 4 you're representing there's --	3 evidence here? 4 MR. MURGATROYD: Yes.
5 MR. MURGATROYD: I asked if he's aware 11:18:07 6 that such assertions have been made?	5 MS. CONNELLY: Okay. Plaintiff's Exhibit 11:20:05 6 63 --
7 MS. CONNELLY: I'm not aware that such 8 a -- that's a fact that's not in evidence. You 9 can ask him, are you aware that any have been 10 made -- 11:18:16	7 MR. MURGATROYD: I think it's -- yes, it's 8 63? Correct?
11 MR. MURGATROYD: Fine. I'll take your 12 question.	9 MS. CONNELLY: -- is an incomplete chart 10 of unknown origin, not bates stamped numbered. 11:20:16 11 Is this something that Counsel prepared?
13 BY MR. MURGATROYD:	12 MR. MURGATROYD: I didn't prepare it. 13 BY MR. MURGATROYD:
14 Q. Are you aware of any assertions that have 15 been made publicly that you were paid by GSK to do 11:18:20 16 the blinded review that ultimately ended up in the 17 Apter paper?	14 Q. Okay. Do you recognize or have you ever 15 seen that document which we've marked as Exhibit 62? 11:20:58
18 A. Not to the best of my knowledge, but my 19 review was blinded and so it's a little bit 20 challenging to see how -- see how -- it's a little 11:18:37 21 bit challenging to see how that influences the 22 paper.	17 Q. Okay. And can you identify for the record 18 what it is? 19 A. It's a letter from Dr. Janet Woodcock, 20 Director, Center for Drug Evaluation and Research -- 11:21:11 21 I'm sorry -- it's directed to Dr. Janet Woodcock, 22 I'm sorry, the director of the Center for Drug 23 Evaluation and Research, FDA. It is from Merrill 24 Goozner, G-O-O-Z-N-E-R, Director, Integrity in 25 Science Project at the Center for Science in the 11:21:22
23 Q. I'm not asking whether it influenced the 24 paper. I'm just want to know whether or not -- 25 yesterday you testified you were not paid, and I'm 11:18:41	Page 101
Page 99	Page 101
1 just saying there's allegations -- 11:18:44	1 Public Interest, and it's ccd to several other 11:21:22 2 people.
2 A. No. I think yesterday I said, to the best 3 of my knowledge I wasn't paid. I'm not certain I 4 wasn't. I don't think I was.	3 Q. Okay. And is it requesting that you don't 4 participate in the 2004 Advisory Committee meeting 5 held by the FDA? 11:21:37
5 Q. Okay. Well, let's take a look at this 11:18:58 6 document. Do you recall -- well, let's just take a 7 look at the document. We're up to 62.	6 A. No. 7 Q. What is it? What is the purpose of that 8 letter?
8 (Ryan Deposition Exhibit No. 62 9 was marked for identification).	9 A. I'm sorry. This is different than a 10 letter I had seen before. Yes. It is requesting 11:21:50 11 that I not participate in that meeting.
10 MR. DAVIS: May I see it? 11:19:28	12 Q. Okay. And what are the grounds that are 13 alleged in the letter why you should not 14 participate?
11 MS. CONNELLY: Yes. Sure.	15 A. It's the -- it is -- of course, at this 11:22:09 16 point I had already been adjudicated to be in 17 conflict and so it was known I was not going to be 18 participating there, and what it says the grounds I 19 should not participate in there was that I was a 20 consultant to GSK, maker of Paxil, paid by Glaxco to 11:22:14 21 evaluate the data on Paxil suicidality and to design 22 further studies on use of that drug.
12 MR. DAVIS: This doesn't come close to 13 what you're purporting to representant what you 14 say it represents.	23 I certainly evaluated -- I certainly did 24 evaluate the data on Paxil and suicidality and I 25 said yesterday I didn't think I was paid, but was 11:22:28
15 MR. MURGATROYD: I move to strike 11:19:33 16 Counsel's comments.	
17 MR. DAVIS: You can strike away.	
18 MS. CONNELLY: Well, Plaintiffs Exhibit 62 19 is not bates numbered. It's a January 30, 2004 20 letter from an organization known as CSPI. 11:19:52	
21 (Ryan Deposition Exhibit No. 62, 63 22 was marked for identification.)	
23 BY MR. MURGATROYD:	
24 Q. Let me show you what I've marked as 25 Exhibit 63 also, which is from a web site. So you 11:20:03	

Page 102	Page 104
<p>1 not certain. You saw all my 1099s and if so it was 11:22:29</p> <p>2 a modest amount of money, and I certainly talked to</p> <p>3 you about designing prior studies; certainly, I have</p> <p>4 not been designing any further studies of that trial</p> <p>5 -- 11:22:31</p> <p>6 Q. Okay. And --</p> <p>7 A. -- so I was conflicted out at the time. I</p> <p>8 think I was not paid, but if so it was minimus and I</p> <p>9 hadn't designed any other things, and this is from a</p> <p>10 group that we don't know. 11:22:33</p> <p>11 Q. Okay. What do you mean, we don't know?</p> <p>12 A. A group that I don't know. I was using</p> <p>13 the word we I'm suppose. My mistake.</p> <p>14 Q. Okay.</p> <p>15 A. What is the group? 11:23:14</p> <p>16 Q. What? It says right there what the group</p> <p>17 is.</p> <p>18 A. Yes, but I mean it doesn't say what the</p> <p>19 group is. It says their name. What do they do?</p> <p>20 Q. You know as well as I do, Doctor. I don't 11:23:16</p> <p>21 know. I was supplied the information.</p> <p>22 MS. CONNELLY: Supplied to us.</p> <p>23 BY MR. MURGATROYD:</p> <p>24 Q. And now a minute ago we talked about the</p> <p>25 \$541,000 that was paid to your university for 11:23:22</p>	<p>1 questions about it. 11:24:16</p> <p>2 MS. CONNELLY: Okay. Exhibit 64 looks</p> <p>3 like a progress report.</p> <p>4 THE WITNESS: Okay.</p> <p>5 BY MR. MURGATROYD: 11:24:35</p> <p>6 Q. And can you identify for the record, sir,</p> <p>7 what that document is?</p> <p>8 A. This is a progress report to the</p> <p>9 Institutional Review Board at the University of</p> <p>10 Pittsburgh talking about -- it would be a document 11:24:48</p> <p>11 you submit annually to the IRB talking about any</p> <p>12 recruitment and significant side effects dated</p> <p>13 November 14, 1995.</p> <p>14 Q. Okay. And is that document authentic?</p> <p>15 A. It appears to be so. 11:25:16</p> <p>16 Q. Okay. And it was prepared by you or on</p> <p>17 your behalf?</p> <p>18 A. Yes.</p> <p>19 Q. And does it discuss how many subjects you</p> <p>20 had in your study? 11:25:22</p> <p>21 A. It is just how many subjects we had</p> <p>22 enrolled as of November 14, 1995.</p> <p>23 Q. Okay. And what was that number?</p> <p>24 A. 25.</p> <p>25 Q. And do you recall enrolling any subjects 11:25:31</p>
Page 103	Page 105
<p>1 conducting 329, correct? 11:23:28</p> <p>2 A. Yes.</p> <p>3 Q. And how much of that breaks down to per</p> <p>4 adolescent that participated in the study?</p> <p>5 A. We weren't paid per adolescent so we'll 11:23:39</p> <p>6 have to do the calculations and get you those</p> <p>7 numbers.</p> <p>8 Q. Okay. Remember yesterday you said you</p> <p>9 didn't know how many patients you had in Study 329?</p> <p>10 A. Yes. I said my best estimate was about 11:23:52</p> <p>11 30.</p> <p>12 Q. Okay. Let me show you what I've marked as</p> <p>13 the next exhibit.</p> <p>14 (Ryan Deposition Exhibit No. 64</p> <p>15 was marked for identification.) 02:47:32</p> <p>16 MS. CONNELLY: Are you not going to ask</p> <p>17 him any questions about the Internet chart?</p> <p>18 MR. MURGATROYD: No. It's stupid. He</p> <p>19 answered my question.</p> <p>20 MS. CONNELLY: Okay. 11:24:07</p> <p>21 MR. MURGATROYD: We can strike exhibit --</p> <p>22 what exhibit was it?</p> <p>23 MS. CONNELLY: It must have been 63.</p> <p>24 MR. MURGATROYD: We can strike Exhibit 63</p> <p>25 from the record. I'm not going to ask him any 11:24:11</p>	<p>1 after that date? 11:25:35</p> <p>2 A. I do not remember when enrollment ended;</p> <p>3 clearly, you have that information and it would be</p> <p>4 helpful if you would give it to me.</p> <p>5 Q. No. I'm asking you? How would I know? 11:25:48</p> <p>6 MS. CONNELLY: Asked and answered. He</p> <p>7 said he doesn't remember.</p> <p>8 BY MR. MURGATROYD:</p> <p>9 Q. Okay. And this document that you have</p> <p>10 talks about the number of adverse events that 11:25:59</p> <p>11 occurred to the adolescents who were participating</p> <p>12 in your trial? Right?</p> <p>13 A. Yes.</p> <p>14 Q. And it --</p> <p>15 A. It actually talks not about the number, 11:26:07</p> <p>16 but also about the individual ones.</p> <p>17 Q. Okay. And it talks about an individual</p> <p>18 who attempted suicide? Correct?</p> <p>19 A. That's correct.</p> <p>20 Q. And the IRB. Can you explain to the jury 11:26:14</p> <p>21 what an IRB is?</p> <p>22 A. Sure. Studies conducted in the United</p> <p>23 States, and other countries have paralleled it,</p> <p>24 require an independent review board by an</p> <p>25 Institutional Review Board that looks at the 11:26:29</p>

<p style="text-align: right;">Page 106</p> <p>1 scientific validity of the study, that you are 11:26:31 2 informing patients correctly about the risks and 3 benefits and that the risks and benefits have not 4 materially changed, the best data of the risks and 5 benefits haven't materially changed over the course 11:26:43 6 of the study. 7 Q. And the risk level for your study was 8 raised, correct, at some point during the study? 9 MR. DAVIS: Object to the form. 10 THE WITNESS: Again, this is more than a 11:27:01 11 decade ago so I don't know the answer to your 12 question. I'll have to refresh my memory, 13 please. 14 (Ryan Deposition Exhibit No. 65 15 was marked for identification.) 02:47:32 16 MR. MURGATROYD: Okay. Let's look at 17 Exhibit 65. 18 MS. CONNELLY: Counsel, for the record, 19 it's 11:30. I don't care how you choose to 20 spend you last half hour, but it's up to you. 11:27:24 21 MR. DAVIS: Can I see the document? 22 MS. CONNELLY: Oh, sorry. 23 MR. DAVIS: Thank you, Doctor. 24 BY MR. MURGATROYD: 25 Q. Okay. Can you identify for the record, 11:28:37</p>	<p style="text-align: right;">Page 108</p> <p>1 to do that. 11:29:52 2 Q. Okay. And is that document authentic? 3 A. Yes. It appears so. 4 Q. Okay. And the question was whether or not 5 the risk level for your study was raised to 11:29:59 6 moderate? Do you recall that? 7 A. That was the question and the answer was 8 yes. 9 Q. Okay. And what does that mean when you 10 have a risk level of moderate? I mean, your study 11:30:11 11 didn't start off as a risk level of moderate, 12 correct? 13 A. Yes. That's correct. 14 Q. What did it start off as? 15 A. It would have started off as minimal risk. 11:30:16 16 Q. And then at some point it got raised to 17 moderate? 18 A. Yes. 19 Q. Okay. And why does that occur? 20 A. Yes. It occurred because through this 11:30:18 21 time the IRBs were redefining what they called mild, 22 moderate and severe risks, and they decided that any 23 study where you're giving medication to children was 24 no longer considered minimal. 25 Q. Okay. Did it also have anything to do 11:30:41</p>
<p style="text-align: right;">Page 107</p> <p>1 sir, what that document is? 11:28:37 2 A. This is a memo from myself to the 3 vice-chair at the IRB at the University of 4 Pittsburgh dated January 4, 1996 referencing the 5 same IRB. They had sent me back a memo and -- I'm 11:28:50 6 sorry, I said that vice-versa -- a memo from the 7 vice-chair of the Committee to me about the IRB 8 submission, the annual IRB submission, and they had 9 the following comments and they wanted to re-review 10 it before final re-approval. 11:29:18 11 Their first one it says on the cover 12 sheet. The level of risk should be moderate", and 13 the second one it says in the progress report, "The 14 subjects are not fully accounted for in the report: 15 25 entered the study, and 18 completed the acute 11:29:26 16 phase. Please describe what happened to the 7 not 17 completing the acute phase." 18 It asked me to address this with two 19 copies. So this would have been something they 20 considered straightforward, because the Full Board 11:29:39 21 Review is anything they considered significant. 22 This was reviewed by the chairman to see that that 23 addressed those two points adequately. 24 Q. Okay. And -- 25 A. And the rest of that is just my submission 11:29:52</p>	<p style="text-align: right;">Page 109</p> <p>1 with the fact that a child -- an adolescent in your 11:30:43 2 study tried to kill themselves on the drug? 3 A. My knowledge is the way I said it. I 4 don't know whether the one suicide attempt was 5 contributory to that change or not, but they were 11:30:52 6 changing for all the studies through this interval. 7 Q. Okay. Thank you. 8 MR. MURGATROYD: I think I'll reserve the 9 rest of my time and let Mr. Davis go forth. 10 Are we going to 12:00 today or 12:30? 11:31:09 11 MS. CONNELLY: We had said 12:00, but 12 that's a short time to start. Do you want to 13 go to 12:00? Do you want a full hour before 14 lunch? 15 MR. DAVIS: No. I would just assume to 11:31:09 16 stop now. 17 MS. CONNELLY: Have lunch now? 18 MR. DAVIS: Do lunch now. 19 MR. MURGATROYD: Whatever you guys want 20 works for me guys. 11:31:09 21 MS. CONNELLY: Okay. Let's do it. 22 VIDEOGRAPHER: We're going off the record. 23 The time is approximately 11:32 a.m. 24 (Luncheon Recess taken.) 25 VIDEOGRAPHER: We're back on the record. 12:49:43</p>

Page 114		Page 116	
1	that I object to this line of questioning	12:54:20	1 BY MR. DAVIS: 12:55:52
2	because it exceeds the scope of direct		2 Q. And have you kept -- are you familiar with
3	examination, and I think we've agreed for the		3 that scientific literature that addresses that
4	record that those objections are -- it's going		4 issue?
5	to be a continuing objection to the degree it	12:54:20	5 A. I'm familiar with much of it; clearly, 12:56:05
6	occurs. I don't have to make it each time.		6 there were papers I don't know.
7	MR. DAVIS: All objections except to the		7 Q. Let's look on page 1579 at the second
8	form of the question or the responsiveness of		8 highlight. Can you read that highlight into the
9	the answer are reserved until such further use		9 record, please?
10	at deposition or until time of trial. And for	12:54:31	10 A. "The reports that SSRIs are efficacious 12:56:20
11	the record there is no limit on what I get to		11 for the treatment of adults with MDD (e.g.,
12	ask the witness even though you've noticed the		12 Greenberg et al., 1994,) together with the findings
13	deposition. I'm not limited to your direct		13 that SSRIs have a relatively benign side effect
14	examination in any respect.		14 profile, low lethality after an overdose, and easy
15	MR. MURGATROYD: We'll take that up with	12:54:48	15 administration (once a day) have facilitated the use 12:56:33
16	the judge.		16 of SSRIs in children and adolescents. In fact, from
17	MR. DAVIS: Well, there's been no		17 1989 to 1994 SSRI prescriptions for these
18	agreement to that certainly.		18 populations by physicians has increased fourfold
19	MR. MURGATROYD: Well, I think --		19 (data obtained from the National Disease and
20	BY MR. DAVIS: 12:54:58		20 Therapeutic Index, 1994)." 12:56:50
21	Q. Dr. Ryan. Dr. Ryan, are pediatric -- let		21 Q. Why do SSRIs have low lethality in
22	me start again.		22 overdose?
23	In 1996 were pediatric patients with		23 MR. MURGATROYD: Objection; calls for
24	depression and other psychiatric disorders over		24 speculation.
25	treated or under treated in the United States?	12:55:07	25 THE WITNESS: The statement there was both 12:57:13
Page 115		Page 117	
1	MR. MURGATROYD: Objection; calls for	12:55:13	1 in absolute terms, but it was also referring to 12:57:13
2	speculation.		2 lethality in overdose of tricyclic
3	THE WITNESS: There were several published		3 antidepressants, which was the treatment
4	data sets at the time strongly demonstrating		4 available before this.
5	that they were under treated. About one in	12:55:14	5 I had published papers on this as had 12:57:14
6	five got treatment.		6 many of my colleagues that tricyclic overdoses
7	BY MR. DAVIS:		7 had -- are remarkably lethal even in relatively
8	Q. And were you aware of those data sets at		8 small fold overdoses from primarily
9	the time that you published this --		9 cardiovascular deaths. Those were hard to
10	A. Yes, I was. 12:55:24		10 treat even if the kid got to the hospital -- 12:57:26
11	Q. -- article?		11 even if the child got to the hospital.
12	A. Yes, I was.		12 BY MR. DAVIS:
13	Q. Okay. And --		13 Q. Are -- in terms of comparing SSRIs
14	MS. CONNELLY: Be careful to wait until he		14 including Paxil to tricyclic antidepressants or
15	finishes. 12:55:26		15 TCAs, how do the two compare in terms of which one 12:57:43
16	THE WITNESS: My apologies.		16 is more or less lethal in overdose?
17	BY MR. DAVIS:		17 A. In animal models and in experience with
18	Q. Are pediatric patients with depression and		18 overdose kids, children who come to the emergency
19	other psychiatric disorders over treated or under		19 room with overdose, the SSRIs are very much less
20	treated today, ten years later? 12:55:39		20 lethal than tricyclics in overdose. 12:58:05
21	MR. MURGATROYD: Object; calls for		21 Q. In your experience as a psychiatrist who
22	speculation.		22 has done research in depressive -- in psychiatric
23	THE WITNESS: The published literature		23 disorders in children and adolescents, what is it of
24	strongly supports the contention that on		24 concern to you in terms of giving a tricyclic or a
25	average they're under treated. 12:55:46		25 TCA to a depressed pediatric patient? 12:58:24

<p style="text-align: right;">Page 118</p> <p>1 MR. MURGATROYD: Objection; leading. 12:58:29</p> <p>2 THE WITNESS: There are now -- after the</p> <p>3 Keller et al., article, two concerns. After</p> <p>4 the Keller et al., article and after the</p> <p>5 Med Analyses of Agnell two concerns; one of 12:58:41</p> <p>6 which is the data suggested tricyclic</p> <p>7 antidepressants aren't effective. At -- during</p> <p>8 the time this paper was written in 1996 that</p> <p>9 would not have been my assessment of the</p> <p>10 literature. That's just with more results 12:58:59</p> <p>11 coming in.</p> <p>12 So the first one is there's just no</p> <p>13 evidence that the tricyclics treat</p> <p>14 antidepressants -- I'm sorry -- treat</p> <p>15 depression. The second one is that the risk of 12:59:09</p> <p>16 death in kids taking tricyclics was so much</p> <p>17 higher.</p> <p>18 BY MR. DAVIS:</p> <p>19 Q. Is that risk of death and overdose?</p> <p>20 A. Risk of death and overdose, yes. 12:59:22</p> <p>21 Q. Is this a concern that the physician is</p> <p>22 placed in the situation -- in terms of trying to</p> <p>23 treat the depression actually giving the pediatric</p> <p>24 patient a medication which they, in fact, they may</p> <p>25 use to harm themselves in overdose? 12:59:35</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. So was it your assessment in 1996 that 01:00:52</p> <p>2 prescriptions of SSRIs in children and adolescents</p> <p>3 were, in fact, increasing because of the fact that</p> <p>4 there's relatively -- they have a relatively benign</p> <p>5 side effect, low lethality in overdose, and the fact 01:01:05</p> <p>6 that they were shown to be efficacious for the</p> <p>7 treatments of adults with major depressive disorder?</p> <p>8 A. I think yes, yes, and sort of. It was my</p> <p>9 assessment they were increasing because of the low</p> <p>10 lethality. That was a very big deal. It was my 01:01:24</p> <p>11 assessment, the sort of one, is that tricyclics has</p> <p>12 also been shown to be effective in adults, and so I</p> <p>13 don't know -- I don't know that the effectiveness</p> <p>14 was nearly a push as the safety issues. That was a</p> <p>15 big deal. 01:01:43</p> <p>16 Q. Okay. Now, was this increase in the</p> <p>17 prescription rate of SSRIs for treatment of children</p> <p>18 and adolescents with major depressive disorders</p> <p>19 occurring before Study 329 was ever commenced?</p> <p>20 A. Yes. Before it was commenced? Yes. 01:02:05</p> <p>21 Q. And was it occurring before the data had</p> <p>22 ever come in on Study 329?</p> <p>23 A. Yes.</p> <p>24 Q. And was it occurring before you and your</p> <p>25 colleagues had ever analyzed the data for the first 01:02:16</p>
<p style="text-align: right;">Page 119</p> <p>1 A. Yes. There's even a week -- even a week's 12:59:41</p> <p>2 worth of tricyclic antidepressants could be lethal</p> <p>3 in overdose.</p> <p>4 Q. Okay. Let me ask you a question</p> <p>5 concerning the statement that you have here that 12:59:48</p> <p>6 says, "In fact from 1989 until 1994 SSRI</p> <p>7 prescriptions for these populations by physicians</p> <p>8 have increased by fourfold." What's the basis of</p> <p>9 that statement?</p> <p>10 A. That was -- there are registraries. There 01:00:05</p> <p>11 are commercial registraries that accumulate the</p> <p>12 usage data of how many prescriptions for different</p> <p>13 age groups are given for different compounds, and</p> <p>14 that was from that sort of a source.</p> <p>15 Q. And the patient population that's being 01:00:26</p> <p>16 discussed is children and adolescents?</p> <p>17 A. I do not remember. We would have to look</p> <p>18 at the original citation.</p> <p>19 Q. It's in the preview section.</p> <p>20 A. I'm sorry. I assume it's children and 01:00:37</p> <p>21 adolescents. I do not remember that particular</p> <p>22 citation so presumably so, but I don't remember it</p> <p>23 enough and we would have to go and check the</p> <p>24 citation to see if it's referring to both or just to</p> <p>25 adolescents. 01:00:48</p>	<p style="text-align: right;">Page 121</p> <p>1 time in November of 1997 when you had the clinical 01:02:22</p> <p>2 investigator meeting?</p> <p>3 A. Yes.</p> <p>4 Q. And so is it fair to say that regardless</p> <p>5 of what was happening at that time with the study 01:02:31</p> <p>6 called 329 that physicians were using SSRIs to treat</p> <p>7 children and adolescents with major depressive</p> <p>8 disorders irrespective of any publications</p> <p>9 concerning -- or completed studies concerning use of</p> <p>10 SSRIs in children and adolescents? 01:02:48</p> <p>11 A. Yes.</p> <p>12 MR. MURGATROYD: Objection; calls for</p> <p>13 speculation.</p> <p>14 THE WITNESS: I'm sorry.</p> <p>15 BY MR. DAVIS: 01:03:05</p> <p>16 Q. You mentioned that -- just for the jury's</p> <p>17 benefit -- you mentioned that SSRIs have low</p> <p>18 lethality in overdose. What do you mean by that?</p> <p>19 A. Yes. If you take a big overdose of any of</p> <p>20 the compounds in this class of Serotonin Reuptake 01:03:24</p> <p>21 Inhibitors almost everybody who does that, unless</p> <p>22 they take it with other compounds, lives.</p> <p>23 Q. Let me turn your attention to page 1580</p> <p>24 where I've highlighted the next portion, and then if</p> <p>25 I could, if I could just ask you to read the very 01:03:39</p>

	Page 122		Page 124
<p>1 first sentence that's highlighted? 01:03:43</p> <p>2 A. "Prevention of depression for children and</p> <p>3 adolescents at high risk of developing depression,</p> <p>4 such as the offspring of depressed parents and</p> <p>5 children with depressive symptomatology, but not 01:03:52</p> <p>6 clinical depression is of prime importance."</p> <p>7 Q. Why is that of prime importance?</p> <p>8 A. The argument saying it's of prime</p> <p>9 importance is because depression was then and is now</p> <p>10 known to be strongly recurrent, and then as now 01:04:14</p> <p>11 there was reasonable, but not overwhelming data that</p> <p>12 each future episode made it easier to get a</p> <p>13 subsequent episode; in addition, obviously people</p> <p>14 are at more risk for a completed suicide -- a child</p> <p>15 who has depressions in their life is at more risk 01:04:31</p> <p>16 for completed suicide during the depression and</p> <p>17 about 60 percent of suicides in youth seem -- appear</p> <p>18 to be secondary to a depressive episode.</p> <p>19 (Ryan Defendants Deposition Exhibit</p> <p>20 No. 2, 3,4 were marked for identification.) 01:04:46</p> <p>21 Q. Doctor, I'm going to hand you what has</p> <p>22 been marked as Defendants Exhibits 2, 3, and 4, and</p> <p>23 ask you if those are fair and accurate</p> <p>24 representations of the highlighted portions of your</p> <p>25 article that you just read into the record in 01:05:11</p>	<p>1 not your presentation, it's your slides? 01:06:39</p> <p>2 Right?</p> <p>3 MR. DAVIS: I'll rephrase.</p> <p>4 THE WITNESS: I'm very sorry, guys.</p> <p>5 MR. DAVIS: Are you okay? 01:06:46</p> <p>6 THE WITNESS: I'm as good as I'm going to</p> <p>7 be. Go for it.</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. Is Exhibit 42 a copy of the slides that</p> <p>10 you prepared for grand rounds at the University of 01:07:01</p> <p>11 Texas in Galveston, Department of Psychiatry, in</p> <p>12 July of 1999?</p> <p>13 A. Yes.</p> <p>14 Q. All right. Let me ask you a few -- and</p> <p>15 when you presented these slides, how did you do 01:07:11</p> <p>16 that?</p> <p>17 A. Yes. Like I would always do. You present</p> <p>18 the slides and then use those as prompts to discuss</p> <p>19 the question in more detail.</p> <p>20 Q. Let me ask you some questions. The slide 01:07:26</p> <p>21 on the first page down at the bottom left-hand</p> <p>22 corner?</p> <p>23 A. Yes.</p> <p>24 Q. What's the title of that slide?</p> <p>25 A. It say, "The important bits." 01:07:33</p>		
<p>1 response to my questions? 01:05:14</p> <p>2 A. Yes, they are.</p> <p>3 Q. Thank you.</p> <p>4 MS. CONNELLY: Do you want one?</p> <p>5 THE WITNESS: No. I've got one. 01:06:18</p> <p>6 MS. CONNELLY: Okay.</p> <p>7 THE WITNESS: I've got one. It just takes</p> <p>8 a while to stop.</p> <p>9 MR. DAVIS: Ms. Connelly, could you find</p> <p>10 Exhibit 42? It's the grand rounds presentation 01:06:18</p> <p>11 that Dr. Ryan provided?</p> <p>12 MS. CONNELLY: Yes.</p> <p>13 MR. DAVIS: Thank you.</p> <p>14 BY MR. DAVIS:</p> <p>15 Q. Doctor, I'm going to hand you what has 01:05:14</p> <p>16 been marked as Exhibit 42 to your deposition. Is</p> <p>17 this a copy of a presentation that you provided at</p> <p>18 grand rounds at the University of Texas in Galveston</p> <p>19 in July of 1999?</p> <p>20 A. Yes, it is. 01:06:31</p> <p>21 Q. All right. Let me ask you just a few</p> <p>22 questions about some of the slides that are</p> <p>23 presented here.</p> <p>24 MS. CONNELLY: I'm going to have a late</p> <p>25 objection. Object to the form, because it's 01:06:39</p>	<p>1 Q. And, please, if you could for the jury, 01:07:33</p> <p>2 read in there what are the important bits that you</p> <p>3 had on that slide?</p> <p>4 A. It says, "An episode of depression is bad;</p> <p>5 suffering, psychosocial impairment and suicide." 01:07:33</p> <p>6 Q. Let me stop you right there: Do you know</p> <p>7 what the suicide rates are in children or</p> <p>8 adolescents?</p> <p>9 A. The suicide rate in young children is</p> <p>10 quite small. The suicide rate in adolescents has 01:07:59</p> <p>11 gone down in the past decade.</p> <p>12 Q. Do you know why? Have there been any</p> <p>13 studies looking at how prescription medications have</p> <p>14 affected the suicide rates?</p> <p>15 MR. MURGATROYD: Objection; lack of 01:08:14</p> <p>16 foundation and calls for speculation.</p> <p>17 THE WITNESS: I am aware of several</p> <p>18 studies on the matter.</p> <p>19 BY MR. DAVIS:</p> <p>20 Q. What studies are you aware of? 01:08:24</p> <p>21 A. Yes. There is on the FDA web site</p> <p>22 pointing to an original article who -- I'm</p> <p>23 forgetting the author of -- there's the correlation</p> <p>24 between -- there's the temporal correlation</p> <p>25 suggesting that overall in this country completed 01:08:33</p>		

<p style="text-align: right;">Page 126</p> <p>1 suicide in youth dropped about the time of 01:08:37</p> <p>2 introduction of SSRIs.</p> <p>3 There's a second study that looked over a</p> <p>4 10-year period, from 1991 to 2001, at the</p> <p>5 interrelationship within ZIP codes of the uptake of 01:08:50</p> <p>6 SSRIs and the rate of completed suicide finding a</p> <p>7 correlation between the time of uptake of SSRIs and</p> <p>8 a decrease in hazard for suicide.</p> <p>9 Q. To summarize. Do those studies</p> <p>10 essentially show that as prescriptions of selective 01:09:16</p> <p>11 serotonin Reuptake inhibitors have increased that</p> <p>12 the suicide rate has decreased?</p> <p>13 MR. MURGATROYD: Let me object on the</p> <p>14 grounds that those studies has been proven to</p> <p>15 be -- have shown to be false and that any 01:09:35</p> <p>16 statement based on those studies would be</p> <p>17 equally false.</p> <p>18 BY MR. DAVIS:</p> <p>19 Q. You may answer.</p> <p>20 A. Yes. The studies are evidence in that 01:09:37</p> <p>21 direction, but like all studies considered</p> <p>22 separately they're just evidence in that direction.</p> <p>23 I don't know that they definitely show -- I don't</p> <p>24 know that they reached a level of proof.</p> <p>25 Q. But do they show a trend? 01:09:48</p>	<p style="text-align: right;">Page 128</p> <p>1 that have been done looking at how often teenagers 01:10:59</p> <p>2 or youth think about suicide?</p> <p>3 A. The data suggests that about 20 percent of</p> <p>4 adolescents think about suicide each year.</p> <p>5 Q. What type of analyses are you referring 01:11:20</p> <p>6 to?</p> <p>7 A. I know the secondary parts on that so I</p> <p>8 can't answer that question about it.</p> <p>9 Q. Now, let's look at "Important Bits" number</p> <p>10 two. Can you read that bullet point, please? 01:11:33</p> <p>11 A. Sure. It says "Depression is recurrent</p> <p>12 and the more one has the more one gets in the</p> <p>13 future."</p> <p>14 Q. Can you explain that to the jury if you</p> <p>15 would, please? 01:11:46</p> <p>16 A. Yes. Again, this is for a slide so it's</p> <p>17 informal language, but what it's is that there's</p> <p>18 evidence in children and adolescents that each</p> <p>19 depressive episode makes the next one easier to get,</p> <p>20 and it was also emphasizing again the really 01:12:05</p> <p>21 important majority of children, approximately 70</p> <p>22 percent, will get another depression within five</p> <p>23 years.</p> <p>24 Q. There's a slide that's right next to that,</p> <p>25 just to the right of it that's called "Epidemiology 01:12:20</p>
<p style="text-align: right;">Page 127</p> <p>1 A. Yes, they do. 01:09:52</p> <p>2 Q. And is it --</p> <p>3 A. They show a significant P value. That's</p> <p>4 different than saying they definitively prove the</p> <p>5 question, in my mind. 01:09:59</p> <p>6 Q. Yes. But do they provide evidence --</p> <p>7 A. They do indeed.</p> <p>8 Q. Let me -- do they provide evidence that</p> <p>9 with the increase of prescriptions of SSRIs that</p> <p>10 suicide rates have decreased in both youth and adult 01:10:09</p> <p>11 patients?</p> <p>12 A. I'm aware of the youth ones. I'm aware of</p> <p>13 the youth studies that do provide that evidence.</p> <p>14 I'm not as familiar with the adult studies.</p> <p>15 Q. Now, back to my talking about suicide 01:10:26</p> <p>16 rates in adolescents, are you aware of what the</p> <p>17 suicide rates are now?</p> <p>18 A. Yes. The blended male/female rate in the</p> <p>19 most recent decade is approximately 10 per 100,000</p> <p>20 per year for later adolescents. It's smaller -- 01:10:33</p> <p>21 it's less for younger children.</p> <p>22 Q. Are you aware of any studies that have</p> <p>23 looked at how often teenagers or -- let me strike my</p> <p>24 question.</p> <p>25 Are you aware of any studies or analyses 01:10:52</p>	<p style="text-align: right;">Page 129</p> <p>1 of Child Depression", do you see it? 01:12:22</p> <p>2 A. Yes.</p> <p>3 Q. And there's a bullet there. The second</p> <p>4 bullet. Can you read that for the jury, please?</p> <p>5 A. Yes. It says "Lifetime prevalence in 01:12:24</p> <p>6 adolescents 15 to 20 percent."</p> <p>7 Q. What type of information are you trying to</p> <p>8 convey?</p> <p>9 A. I'm trying to convey that the data at the</p> <p>10 time would suggest that by someone who was reaching 01:12:39</p> <p>11 age 18 or 20 approximately 1 in 5 would have had one</p> <p>12 or more life-time depressions.</p> <p>13 Q. Is there any new data out that changes</p> <p>14 those figures?</p> <p>15 A. The National Co-morbidity Survey data of 01:12:50</p> <p>16 Dr. Kessler and colleagues got a number that was</p> <p>17 slightly higher than that I believe.</p> <p>18 Q. Do you know what the slightly number is?</p> <p>19 A. I think it was 25 percent.</p> <p>20 MR. MURGATROYD: I want to make sure it's 01:12:50</p> <p>21 clear. GSK didn't Cross-Notice Dr. Ryan's</p> <p>22 deposition, did it?</p> <p>23 MR. DAVIS: It doesn't matter. I don't</p> <p>24 care.</p> <p>25 MS. CONNELLY: Counsel, yesterday you said 01:13:09</p>

<p style="text-align: right;">Page 130</p> <p>1 on the record that this wasn't a deposition for 01:13:09 2 use at trial.</p> <p>3 MR. MURGATROYD: I'm just asking whether 4 or not GSK Cross-Noticed it.</p> <p>5 MS. CONNELLY: I'm just confused, because 01:13:28 6 yesterday you said that it wasn't, and so it 7 sounds like today you're trying to say it is.</p> <p>8 MR. MURGATROYD: No. I'm just asking 9 whether or not GSK Cross-Noticed Dr. Ryan's 10 deposition? 01:13:35</p> <p>11 MR. DAVIS: It's not necessary to 12 Cross-Notice it. Just like it's not necessary 13 for your firm to Cross-Notice depositions that 14 we Notice in order for you to use those 15 depositions. Otherwise -- 01:13:37</p> <p>16 MR. MURGATROYD: I'm just questioning? Do 17 you agree that you did not?</p> <p>18 MR. DAVIS: I want to ask a question. 19 BY MR. DAVIS:</p> <p>20 Q. Look at the next slide, Dr. Ryan. There's 01:13:39 21 a slide that talks about "Age of Onset Unipolar and 22 Bipolar Depression."</p> <p>23 A. Yes.</p> <p>24 Q. What information are you trying to convey 25 in that slide? 01:13:59</p>	<p style="text-align: right;">Page 132</p> <p>1 attempts with longer, multi-year duration of 01:14:52 2 depressive episode(s)."</p> <p>3 Q. By that, are you saying that as -- that 4 patients who are adolescents or children who have 5 dysthymic disorders or major depressive disorders 01:15:13 6 have an even more increased risk of suicidality with 7 each episode?</p> <p>8 A. That wasn't --</p> <p>9 MR. MURGATROYD: Objection; leading. 10 BY MR. DAVIS: 01:15:24</p> <p>11 Q. Let me ask it again: What are you trying 12 to convey by that?</p> <p>13 A. I was referring to a study that I had done 14 with my colleagues at Columbia looking at 192 15 children where most of the suicide attempts were 01:15:35 16 children who had a depression for two years or 17 longer, so talking about the data that suggests the 18 suicide attempts are from the children who don't get 19 better rather than the short duration depressions.</p> <p>20 Q. If a child or adolescent has one or -- has 01:15:50 21 more than one -- strike that.</p> <p>22 A child or adolescent who has more than 23 one depressive episode, are they at increased -- 24 more increased risk of suicidality with each 25 depressive episode? 01:16:11</p>
<p style="text-align: right;">Page 131</p> <p>1 A. Yes. This slide is just a schematic. It 01:13:52 2 is not trying to convey precise numbers. The issue 3 it's trying to convey is that bipolar disorder 4 typically has its first onset somewhere between 15 5 and 25. It can start sooner. It can start later, 01:14:09 6 and unipolar depression, which is more common 7 overall, can start at any decade of life.</p> <p>8 Q. At the bottom of that is a slide that's 9 called "Clinical Picture."</p> <p>10 A. Yes. 01:14:22</p> <p>11 Q. Can you read for the jury the two bullets 12 that you have there?</p> <p>13 A. Bullet Number one: "Dysthymic disorders go 14 on to major depression and 'double depression', 15 which is associated with a more morbid course than 01:14:24 16 MDD alone."</p> <p>17 Q. What is double depression?</p> <p>18 A. Double depression is children who have 19 dysthymia, which is persistent depression, not 20 severe enough to make a major depression and then 01:14:37 21 getting major depression on top. Those children in 22 the Study Covax had the worse course.</p> <p>23 Q. And then the next bullet point, can you 24 read that?</p> <p>25 A. "Increase in suicidal ideation, plans and 01:14:52</p>	<p style="text-align: right;">Page 133</p> <p>1 A. I -- the data may well be done -- known. 01:16:16 2 I do not know if there's data to confirm or 3 disconfirm that.</p> <p>4 Q. Okay. At the top of the "Clinical 5 Picture" let me ask you a few questions about the 01:16:22 6 bullets there. What's the first bullet you have 7 there?</p> <p>8 A. The first bullet says the "Clinical 9 picture in child, adolescent and adult depression is 10 very similar." 01:16:31</p> <p>11 Q. Why do you mean by that?</p> <p>12 A. Yes. That was also referring to the same 13 study that I did while at Columbia University in 14 saying that if you look at all the symptoms in 15 depression in children and adolescents and look at 01:16:43 16 the same symptoms in adults the symptom picture is 17 very similar from children to adolescents to adults.</p> <p>18 Q. And in the next bullet, would you read 19 that for the jury, please?</p> <p>20 A. Yes. The next bullet says, 01:16:52 21 "Endogeneity/melancholic, suicide attempts, 22 lethality of suicide attempts, and impairment of 23 functioning increase with age."</p> <p>24 Q. What information are you trying to convey 25 with that bullet? 01:17:07</p>

<p style="text-align: right;">Page 134</p> <p>1 A. Again, it's results of the same study 01:17:07</p> <p>2 saying that adolescents had more of a few things</p> <p>3 than children do. The things they had more of</p> <p>4 included the so-called endogenous or melancholic</p> <p>5 subtype, and that's typically having to do with 01:17:16</p> <p>6 psychomotor retardation, slowed thinking, several</p> <p>7 other symptoms, and that adolescents had more</p> <p>8 suicide attempts than children with major</p> <p>9 depression. That the suicide attempts were more</p> <p>10 lethal in adolescents than the attempts that existed 01:17:37</p> <p>11 in children and that they had more psychosocial</p> <p>12 functioning in adolescents than those with</p> <p>13 depression compared to depressed children.</p> <p>14 Q. On the next page you have a slide</p> <p>15 entitled, "What were adult major depressive 01:17:46</p> <p>16 disorders like as children."</p> <p>17 A. Yes.</p> <p>18 Q. And can you read what that bullet says?</p> <p>19 A. Says, "Higher rates of many personality</p> <p>20 disorders including avoidant, histrionic, 01:17:46</p> <p>21 narcissistic, and borderline in adults whose</p> <p>22 depression started in children or adolescence."</p> <p>23 Q. Based upon your research that you have</p> <p>24 done in child and adolescent literature, in your</p> <p>25 review of the literature, what happens to children 01:18:14</p>	<p style="text-align: right;">Page 136</p> <p>1 THE WITNESS: If you look on -- the worst 01:19:26</p> <p>2 impairment that you see in an individual may --</p> <p>3 is not terribly useful so let me talk about</p> <p>4 some group averages.</p> <p>5 BY MR. DAVIS: 01:19:35</p> <p>6 Q. Yes. That would be helpful if you could</p> <p>7 talk about some group averages of those things.</p> <p>8 MR. MURGATROYD: Same objection.</p> <p>9 THE WITNESS: Which is that during a major</p> <p>10 depression they have worse school functioning, 01:19:44</p> <p>11 worse home functioning and worse functioning</p> <p>12 with friends on average and that lasts after</p> <p>13 the end of the depression. Also, from our work</p> <p>14 and work of others they have a higher rate of</p> <p>15 pregnancy. They have more smoking and they 01:20:07</p> <p>16 have more substance abuse and they have a</p> <p>17 higher rate of attempted suicide and completed</p> <p>18 suicide.</p> <p>19 BY MR. DAVIS:</p> <p>20 Q. Thank you. Are you aware of the 01:20:26</p> <p>21 literature on where suicide ranks in terms of cause</p> <p>22 of death for adolescents?</p> <p>23 A. Yes.</p> <p>24 Q. And where does suicide rank in cause of</p> <p>25 death of adolescents? 01:20:46</p>
<p style="text-align: right;">Page 135</p> <p>1 and adolescents who are not adequately treated for 01:18:16</p> <p>2 depression when they move into adulthood?</p> <p>3 MR. MURGATROYD: Objection; leading.</p> <p>4 THE WITNESS: There are not separate</p> <p>5 studies to say what happens to the ones who are 01:18:29</p> <p>6 not adequately treated. There are a number of</p> <p>7 studies to say what happens in general to them.</p> <p>8 The data of persistence from adolescents to</p> <p>9 adulthood is found in every study that is</p> <p>10 looked at to the best of my knowledge so 01:18:46</p> <p>11 it's -- it's essentially incontrovertible that</p> <p>12 adolescents with depression grow up to be</p> <p>13 adults with depression. The data on</p> <p>14 school-aged children, pre-adolescents with a</p> <p>15 major depression in our studies and in several 01:18:58</p> <p>16 others is they've grown up to be depressed</p> <p>17 adults. In two other studies they've had more</p> <p>18 psychopathology in general, but not depression,</p> <p>19 per se, at least in adult.</p> <p>20 BY MR. DAVIS: 01:19:11</p> <p>21 Q. What level of impairment have you seen for</p> <p>22 a child or adolescent who has major depressive</p> <p>23 disorder?</p> <p>24 MR. MURGATROYD: Objection; lack of</p> <p>25 foundation. 01:19:26</p>	<p style="text-align: right;">Page 137</p> <p>1 A. Number three. 01:20:48</p> <p>2 Q. And do you recall from the data what's</p> <p>3 number one and what's number two?</p> <p>4 A. I should. Accidents and homicide. That</p> <p>5 was a rising inflection. I'm not certain that I 01:21:03</p> <p>6 recall.</p> <p>7 Q. Now, for suicides, you said suicides are</p> <p>8 the third leading cause of death, and are you aware</p> <p>9 they have more combined deaths from suicides --</p> <p>10 strike that -- 01:21:28</p> <p>11 Are you aware that suicides in adolescents</p> <p>12 is greater than the combined deaths from cancer,</p> <p>13 heart disease, chronic respiratory disease, birth</p> <p>14 defects, strokes, influenza and pneumonia and blood</p> <p>15 poisoning? 01:21:50</p> <p>16 MR. MURGATROYD: Objection; calls for</p> <p>17 speculation.</p> <p>18 THE WITNESS: I have seen what I assume</p> <p>19 you're referring to before, but could I have</p> <p>20 listed all of those? So was I aware of that 01:22:01</p> <p>21 before you asked me. Not entirely, no.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. Are you aware of some of those?</p> <p>24 A. Yes, I was.</p> <p>25 Q. Which ones are you aware of? 01:22:11</p>

<p style="text-align: right;">Page 138</p> <p>1 A. The first three or four medical conditions 01:22:11</p> <p>2 you suggested. I am aware that in general that</p> <p>3 suicide is a bigger cause of death than essentially</p> <p>4 all medical conditions put together.</p> <p>5 Q. Thank you. Have studies -- have clinical 01:22:18</p> <p>6 studies been done to try to establish efficacy of</p> <p>7 tricyclic antidepressants in patients under 18?</p> <p>8 A. Yes.</p> <p>9 Q. And what have the results of those studies</p> <p>10 been? 01:22:59</p> <p>11 A. The results considered separately study by</p> <p>12 study and considered in med analyses have been</p> <p>13 negative.</p> <p>14 Q. Before the introduction of serotonin</p> <p>15 Reuptake inhibitors, in your opinion, were there any 01:23:07</p> <p>16 effective medications available to treat children</p> <p>17 and adolescents who suffer from depression?</p> <p>18 A. In my opinion, no there were not.</p> <p>19 Q. What about the use of cognitive behavior</p> <p>20 therapy or psychotherapy? 01:23:29</p> <p>21 A. Can I go back to your prior question?</p> <p>22 Q. Yes, sir.</p> <p>23 A. I answered it incorrectly. I believe I</p> <p>24 answered it incorrectly by mistake. There was no</p> <p>25 pharmacology treatments with efficacy before. 01:23:39</p>	<p style="text-align: right;">Page 140</p> <p>1 BY MR. DAVIS: 01:24:52</p> <p>2 Q. Are there any limitations which prevent</p> <p>3 patients from -- pediatric patients from undergoing</p> <p>4 cognitive behavior therapy or psychotherapy?</p> <p>5 MR. MURGATROYD: Objection; calls for 01:25:16</p> <p>6 speculation.</p> <p>7 THE WITNESS: The cognitive behavioral</p> <p>8 therapy is not well studied in younger</p> <p>9 children. It's well studied in adolescents.</p> <p>10 There's only a few studies in younger children, 01:25:29</p> <p>11 and there is a question of the cognitive</p> <p>12 maturity for that to work. So I think that's</p> <p>13 an open question. On any one individual case</p> <p>14 they may be willing to do psychotherapy and not</p> <p>15 medications, willing to do medications and not 01:25:43</p> <p>16 psychotherapy, not willing to do either, but</p> <p>17 there are not major limitations that prevent</p> <p>18 children or adolescents from doing</p> <p>19 psychotherapies.</p> <p>20 BY MR. DAVIS: 01:25:59</p> <p>21 Q. Are there enough qualified child and</p> <p>22 adolescent psychiatrists or therapists available if</p> <p>23 every child or adolescent went and used</p> <p>24 psychotherapy as opposed through seeking treatment</p> <p>25 through medication? 01:26:09</p>
<p style="text-align: right;">Page 139</p> <p>1 Q. No. I did ask you -- I asked you whether 01:23:43</p> <p>2 or not there were any effective medications?</p> <p>3 A. Oh, did I answer that question correctly?</p> <p>4 Okay. So I answered the question correct before</p> <p>5 correctly. I'm sorry. Could you tell me your last 01:23:58</p> <p>6 question?</p> <p>7 Q. Yes. What about the use of cognitive</p> <p>8 therapy or behavioral therapy? Has that proven to</p> <p>9 be an effective treatment for adolescents or</p> <p>10 children with depressive disorders? 01:24:16</p> <p>11 MR. MURGATROYD: Objection; calls for</p> <p>12 speculation.</p> <p>13 THE WITNESS: The studies on that,</p> <p>14 the proponents of those have showed that it's</p> <p>15 effective. One recent study, the so-called 01:24:22</p> <p>16 TADS, T-A-D-S, Study led by John Marsh did not</p> <p>17 find cognitive behavioral therapy to be</p> <p>18 effective. Those studies are somewhat limited.</p> <p>19 The TADS Study was well designed compared to a</p> <p>20 realistic control. Many of the other studies 01:24:35</p> <p>21 showing efficacy for -- or, you know,</p> <p>22 presenting efficacy for CTB have not used a</p> <p>23 realistic control compared to weightless</p> <p>24 control or no treatment, which is a less strong</p> <p>25 evidence approach. 01:24:50</p>	<p style="text-align: right;">Page 141</p> <p>1 MR. MURGATROYD: Objection; calls for 01:26:18</p> <p>2 speculation.</p> <p>3 MS. CONNELLY: I join that one.</p> <p>4 THE WITNESS: There has been considerable</p> <p>5 literature saying that there are insufficient 01:26:26</p> <p>6 child therapists, including by the people who</p> <p>7 train -- who've done the studies in cognitive</p> <p>8 behavioral therapy saying that there are</p> <p>9 massively insufficient therapists of any kind</p> <p>10 trained in cognitive behavioral therapy to 01:26:37</p> <p>11 treat patients.</p> <p>12 MR. MURGATROYD: I'm just going to move --</p> <p>13 I'm going to move to strike his answer just on</p> <p>14 a lack of foundation. Actually, the last</p> <p>15 series of -- the last 20 questions no 01:26:50</p> <p>16 foundation has been laid. No articles have</p> <p>17 been identified; therefore, his last 20</p> <p>18 questions and therefore they are improper</p> <p>19 testimony.</p> <p>20 MR. DAVIS: I believe your objections are 01:27:07</p> <p>21 untimely.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. Let me hand you what's been previously</p> <p>24 marked as Exhibit 1 -- excuse me -- Exhibit 60.</p> <p>25 Dr. Ryan, do you see that Exhibit 61 is a copy of 01:27:28</p>

Page 142	Page 144
1 Dr. Thomas Laughren's January 5, 2004 memo? 01:27:44	1 than half of studies of antidepressants in adults 01:29:59
2 A. Yes.	2 for depression failed to show efficacy on compounds
3 Q. And is Dr. Laughren an employee of FDA?	3 that are subsequently shown to be efficacious.
4 A. Yes.	4 Q. And even though a medication does not meet
5 Q. I want you to turn to page -- I think it's 01:28:01	5 the primary end-points in a clinical study, can a 01:30:14
6 6 on yours where it says that -- there should be a	6 medication still provide meaningful, clinical
7 paragraph that reads -- that begins with "The point	7 benefits to patients?
8 I am making"?	8 MR. MURGATROYD: Objection; it's vague,
9 A. Yes.	9 ambiguous, lack of foundation and calls for
10 Q. All right. Look at the second sentence in 01:28:11	10 speculation. 01:30:26
11 that paragraph, and could you read that -- excuse	11 THE WITNESS: It certainly could in
12 me -- the third sentence in that paragraph and will	12 theory.
13 you please read it into the record?	13 BY MR. DAVIS:
14 A. "We at the FDA, however, do not view	14 Q. Okay. And based upon the results of Study
15 negative studies as proof of no benefit." 01:28:28	15 329, did you believe that Paxil could provide 01:30:29
16 Q. Do you view negative studies as proof of	16 meaningful, clinical benefits to patients
17 no benefit?	17 notwithstanding the fact that the two primary
18 A. No.	18 end-points in that clinical study were not met?
19 Q. And do you agree that the fact that a	19 A. Yes.
20 particular study is negative and is not able to 01:28:37	20 Q. And based upon the results of Study of 01:30:46
21 establish efficacy under primary end-points set	21 329, did you believe that Paxil could provide
22 forth in the study means that particular drug is	22 clinical benefit to patients -- strike that.
23 ineffective in treating children or adolescents with	23 Based upon results of Study 329, did you
24 depression?	24 believe that even though Study 329 would not be
25 MR. MURGATROYD: Objection; lack of 01:29:01	25 sufficient to pass regulatory requirements of 01:31:13
Page 143	Page 145
1 foundation. He can answer that question, calls 01:29:01	1 efficacy that it still could provide a significant 01:31:13
2 for speculation.	2 improvement to pediatric patients with major
3 THE WITNESS: No.	3 depressive disorder?
4 BY MR. DAVIS:	4 MR. MURGATROYD: Objection; calls for
5 Q. And do you hold the opinion also for -- 01:29:09	5 speculation, lack of foundation. It's a 01:31:29
6 with respect to Paxil in the studies that have been	6 compound question.
7 conducted on Paxil to treat pediatric patients with	7 THE WITNESS: Yes.
8 major depressive disorders?	8 BY MR. DAVIS:
9 MR. MURGATROYD: Same objection.	9 Q. I want to talk to you about the process by
10 THE WITNESS: I hold that opinion in 01:29:16	10 which you and the other clinical investigators 01:31:44
11 general about studies that a single negative	11 approached GlaxoSmithKline, then SmithKline Beecham
12 study -- because of the way science is	12 about conducting Study 329. All right? And if I
13 designed, because of the way statistics are	13 use the words GSK or SmithKline Beecham I mean
14 done it provides relatively little evidence	14 GlaxoSmithKline, is that acceptable to you?
15 against efficacy. 01:29:28	15 A. Yes. 01:32:11
16 BY MR. DAVIS:	16 Q. All right. Do you recall the -- do you
17 Q. And does the absence of evidence of	17 recall the genesis of the idea to do a study of SSRI
18 effectiveness mean that there is a absence of lack	18 and adolescents with depression?
19 of benefit caused by Paxil?	19 A. At a child depression consortium meeting
20 A. No. 01:29:41	20 Drs. Keller, Strober, myself, and I believe 01:32:24
21 Q. Is it unusual for one or more depression	21 Gittleman-Klein were talking and we all sort of
22 studies to not meet the primary end-points and yet	22 looked at each another and said, we should do a
23 later on efficacy is established in later studies?	23 study. We, from the beginning, wanted to do a
24 A. No. Dr. Pace and others have written that	24 three-arm study. We wanted to do a study of
25 in reviewing FDA studies in recent decades that more 01:29:58	25 tricyclic versus SSRI versus placebo, because we 01:32:41

Page 146	Page 148
<p>1 anticipated that both active compounds would work 01:32:44</p> <p>2 compared to placebos, but the SSRIs would be safer.</p> <p>3 Q. And why did you believe them to be safe?</p> <p>4 A. For the reasons we've discussed, because</p> <p>5 of the cardiotoxic effects of tricyclic 01:32:58</p> <p>6 antidepressants.</p> <p>7 Q. Do you recall either you or any member of</p> <p>8 the principle investigators approaching</p> <p>9 GlaxoSmithKline about conducting the study?</p> <p>10 A. The investigators discussed and agreed for 01:33:13</p> <p>11 Dr. Keller to approach the company.</p> <p>12 Q. And why did the investigators believe it</p> <p>13 was important to conduct this study?</p> <p>14 A. Because there was at the time no published</p> <p>15 studies on these compounds. They were being used a 01:33:28</p> <p>16 lot. We did not have good treatments for</p> <p>17 depression, because the tricyclic antidepressants in</p> <p>18 all the studies were small so we actually wanted to</p> <p>19 look at both together because we thought that</p> <p>20 society needed good treatment in children. 01:33:33</p> <p>21 Q. Do you believe that before Study 329 was</p> <p>22 initiated that Paxil was being used by physicians to</p> <p>23 treat child and adolescent depression?</p> <p>24 A. I certainly knew of children being treated</p> <p>25 with Paxil. I did not have and do not have data on 01:34:09</p>	<p>1 to fund it? 01:35:29</p> <p>2 MR. MURGATROYD: Objection; compound</p> <p>3 question.</p> <p>4 THE WITNESS: I do not remember that we</p> <p>5 were making fundamental design. I don't 01:35:39</p> <p>6 remember whether the fundamental design was</p> <p>7 essentially completed at the time they decided</p> <p>8 to fund it or we were still doing design issue.</p> <p>9 This would not have been a large design issue,</p> <p>10 you know, in terms of -- there would not have 01:35:50</p> <p>11 been large design issues at that point. I</p> <p>12 don't remember.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. Now, did you and the other principle</p> <p>15 investigators participate in any meetings or 01:35:59</p> <p>16 conference calls about how the study would be</p> <p>17 designed and what efficacy variables would be</p> <p>18 analyzed and looked at?</p> <p>19 A. Yes.</p> <p>20 MR. MURGATROYD: Objection; compound. 01:36:16</p> <p>21 THE WITNESS: Yes. We certainly discussed</p> <p>22 efficacy measures as a group.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. Dr. Boris Birmaher works with you at the</p> <p>25 University of Pittsburgh? 01:36:43</p>
<p>Page 147</p> <p>1 the compound -- how many different SSRIs were used. 01:34:09</p> <p>2 Q. Were you involved in the design of Study</p> <p>3 329?</p> <p>4 A. Yes.</p> <p>5 Q. And what was your level of involvement in 01:34:24</p> <p>6 the design?</p> <p>7 A. I was involved as anybody in the design of</p> <p>8 that. It was the subgroup of us that I've</p> <p>9 discussed, including also Dr. Birmaher.</p> <p>10 Q. How would you describe the amount of 01:34:39</p> <p>11 effort that you put into trying to design Study 329</p> <p>12 so we can properly assess efficacy of Paxil and</p> <p>13 imipramine in treating adolescents with major</p> <p>14 depressive disorders?</p> <p>15 A. It was a long weekend retreat plus 01:34:58</p> <p>16 considerable work, you know, on the phone and</p> <p>17 revising things, so presumably two to three weeks of</p> <p>18 full-time work equivalent perhaps.</p> <p>19 Q. And after the initial proposal was made to</p> <p>20 GlaxoSmithKline, did GlaxoSmithKline agree to 01:35:11</p> <p>21 proceed and to fund the study?</p> <p>22 A. Yes.</p> <p>23 Q. And did you and the other clinical</p> <p>24 investigators continue to work on the design of that</p> <p>25 study even after the -- GlaxoSmithKline had agreed 01:35:26</p>	<p>Page 149</p> <p>1 A. He's a colleague with me. We work 01:36:44</p> <p>2 together on some studies; separately on some</p> <p>3 studies.</p> <p>4 Q. Is he a psychiatrist?</p> <p>5 A. He's a child psychiatrist as am I. 01:36:48</p> <p>6 Q. And was he co-principle investigator in</p> <p>7 Study 329?</p> <p>8 A. I don't remember whether he was listed as</p> <p>9 co-investigator or principle investigator. Probably</p> <p>10 co-principal, but I would have to review my notes. 01:36:59</p> <p>11 Q. Before the study began, had you and Dr.</p> <p>12 Birmaher worked on other clinical studies together?</p> <p>13 A. We had worked on other studies. Yes, we</p> <p>14 had worked on other clinical studies.</p> <p>15 Q. And how would you describe the level of 01:37:20</p> <p>16 involvement that you and he had together with</p> <p>17 respect to implementing Study 329 in enrolling</p> <p>18 patients and making sure that the procedures were</p> <p>19 followed?</p> <p>20 A. Yes. I had a larger role in the design of 01:37:29</p> <p>21 the study. He had a larger role in the</p> <p>22 implementation.</p> <p>23 Q. Did you and he at any time discuss how --</p> <p>24 well -- strike that.</p> <p>25 Did you and he at any time during the 01:37:43</p>

	Page 150		Page 152
1 course of the study discuss how patients were during 2 on the medication with the understanding that it was 3 blinded and you did not know which patient was on 4 placebo and patient on Paxil?	01:37:44	5 A. We would of at the time discussed SAEs, 6 severe adverse effects, and other, you know, or 7 things that seemed problematic or otherwise -- 8 otherwise we would not have, and it would have been 9 disadvantages to have large discussions about how 10 patients seem to be doing in a study that you are 11 trying to keep blind, because you don't want to 12 successfully guess.	5 A. No. The average HAM-D score can be 6 extracted from Table two if you look at the means 7 across; for paroxetine was 18.99, for imipramine was 8 18.11, and placebo was 18.97. So mathematically 9 since the cells were about the same the overall mean 10 would be approximately 18.6 for the average Hamilton 11 Score of Admission.
13 Q. Let me hand you what's been marked as 14 Plaintiff's Exhibit 3, which is an article that you 15 co-authored with Dr. Martin Keller about the results 16 of Study 329.	01:37:58 01:38:13 01:38:26	17 MR. MURGATROYD: There were other authors 18 than just Dr. Martin Keller.	11 Q. Now, would you characterize an average 12 Hamilton Depression Rating Score of around 18 to be 13 just mild depression? 01:40:52
19 MR. DAVIS: I said Dr. Keller and others.		20 MS. CONNELLY: I missed that. 01:38:29	14 A. No. 01:41:07
21 BY MR. DAVIS: 22 Q. Is this the article Dr. Keller, yourself, 23 and others authored about the results of Study 329?		24 A. Yes. 25 Q. Now, if you could, would you please turn 01:38:50	15 Q. What does the mean Hamilton Depression 16 Score in Table one tell you concerning the severity 17 of the depression of the patients that were enrolled 18 in Study 329? 19 A. It tells me that on average they were of 20 moderate depression since that's the mean and the 21 least was 12, you know, that some were considerably 22 higher than 18 and some were lower. 23 (Defendants Deposition Exhibit No. 5, 24 6 was marked for identification.) 02:47:32
	Page 151	1 to the section entitled "Patient Eligibility." 2 A. Yes, I have it.	Page 153
3 Q. Now, looking at the bottom part of that 4 paragraph, do you see that it says, "In addition to 5 fulfilling the DSM-4 criteria for major depression, 6 subjects were required to have a total score of at 7 least 12 on the 17-Item Hamilton Rating Scale for 8 Depression"?	01:38:59 01:39:20	9 A. Yes. 10 Q. And were they also required to have other 11 scores on other rating scales? 01:39:33	1 MS. CONNELLY: Exhibit 5 looks like an 2 extract of the article at issue. Have you done 3 that? 4 MR. DAVIS: Yes. I've done that. 5 BY MR. DAVIS: 01:42:29
12 A. Yes. They were required in addition to 13 have a score of less than 60 on the Child's Global 14 Assessment Scale and a score of at least 80 on 15 Picture Peabody Vocabulary Test, which is a rough 16 proxy for an IQ.	01:39:44	17 Q. Now, Plaintiff's Counsel asked you 18 questions about the -- whether children -- strike 19 that.	6 Q. Dr. Ryan, you have been handed what's been 7 marked Exhibits 5 and 6. 8 MR. MURGATROYD: I'm sorry. Which is 9 which? 10 MR. DAVIS: The first one, which is from 11 the abstract is 5 and the other is 6. Okay? 01:42:43
20 Plaintiff's Counsel asked you questions 21 about the HAM-D score for eligible patients who were 22 enrolled in Study 329.	01:40:03	23 A. Yes. 24 Q. And was the average HAM-D score 12, which 25 was the entry criteria? 01:40:18	12 MR. MURGATROYD: Okay. Thank you. 13 BY MR. DAVIS: 14 Q. And let me ask you this. Look at the 15 abstract that's in the Keller article that you were 16 a coauthor on. 01:42:59 17 A. Yes. 18 Q. And in that abstract, does this article 19 identify the primary end-points? 20 A. Yes. 01:43:20 21 Q. What does it say about the primary 22 end-points? 23 A. It's about the second or third sentence 24 into the abstract. It says, "The two outcome 25 measures were endpoint response (Hamilton Rating 01:43:28

<p style="text-align: right;">Page 154</p> <p>1 Scale for Depression [HAM-D] score less than or 01:43:31</p> <p>2 equal to 8 or greater than or equal to 50 percent of</p> <p>3 reduction in baseline HAM-D) and change from</p> <p>4 baseline HAM-D score."</p> <p>5 Q. Now, does Defendants Exhibit 5 accurately 01:43:46</p> <p>6 and fairly represent what you just read out of the</p> <p>7 abstract?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Now, does the Keller article,</p> <p>10 again, identify the primary end-points in the 01:44:03</p> <p>11 section describing the efficacy and safety</p> <p>12 evaluations that's on page 764?</p> <p>13 A. Yes.</p> <p>14 Q. And would you please read what is stated</p> <p>15 in the section entitled "Safety and efficacy about 01:44:24</p> <p>16 the primary end-points"?</p> <p>17 A. "The protocol described two primary</p> <p>18 outcomes measures: (1) response, which was defined</p> <p>19 as HAM-D score of less than or equal to 8 or a</p> <p>20 greater than or equal to 50 percent reduction in 01:44:33</p> <p>21 baseline HAM-D score at the end of treatment; and</p> <p>22 (2) change from baseline in HAM-D total score."</p> <p>23 Q. Now, does Defendants Exhibit 6 fairly and</p> <p>24 accurately represent what you just read from the</p> <p>25 article that you coauthored? 01:45:01</p>	<p style="text-align: right;">Page 156</p> <p>1 BY MR. DAVIS: 01:47:07</p> <p>2 Q. Would it be possible to include all the</p> <p>3 efficacy variables or outcome measures that were</p> <p>4 analyzed in a journal article of this nature?</p> <p>5 MR. MURGATROYD: Objection; calls for 01:47:14</p> <p>6 speculation.</p> <p>7 THE WITNESS: It would not be possible.</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. And why don't you think would that would</p> <p>10 be possible? 01:47:24</p> <p>11 A. Because there's a space limitation.</p> <p>12 Q. Now, does the Table two -- the article</p> <p>13 which you coauthored -- strike that.</p> <p>14 What does Table two outline in the article</p> <p>15 in which you coauthored on the results of Study 329? 01:47:39</p> <p>16 A. Table two looks at the difference between</p> <p>17 paroxetine and placebo and the difference between</p> <p>18 imipramine and placebo on variables related to</p> <p>19 depression and what the mean differences are and</p> <p>20 whether they're statistically significant or not. 01:47:58</p> <p>21 Q. And what depression related variables are</p> <p>22 analysed in Table two?</p> <p>23 A. Whether the Hamilton-D Score was less than</p> <p>24 8 at end-point. The combination criteria, which was</p> <p>25 a primary outcome measure of whether either the 01:48:18</p>
<p style="text-align: right;">Page 155</p> <p>1 A. Yes. 01:45:05</p> <p>2 Q. Okay. Now, I'll hand you what I'm marking</p> <p>3 as Exhibit 7.</p> <p>4 A. Okay.</p> <p>5 (Ryan Defendants Exhibit No. 7 01:45:24</p> <p>6 was marked for identification.)</p> <p>7 BY MR. DAVIS:</p> <p>8 Q. Dr. Ryan, can you take a look at</p> <p>9 Defendants 7 and tell me whether that is a fair and</p> <p>10 accurate representation of Table two that's in the 01:46:01</p> <p>11 article that you coauthored on the results of Study</p> <p>12 329?</p> <p>13 A. Yes, it is.</p> <p>14 Q. What's the title of that table, please,</p> <p>15 sir? 01:46:41</p> <p>16 A. "Mean scores of Depression-Related</p> <p>17 Variables in Adolescents who were treated with</p> <p>18 Paroxetine, Imipramine or Placebo."</p> <p>19 Q. Is that table entitled "All efficacy</p> <p>20 outcomes measures or variables that were analyzed in 01:46:50</p> <p>21 Study 329"?</p> <p>22 MR. MURGATROYD: Objection; the document</p> <p>23 speaks for itself.</p> <p>24 THE WITNESS: No.</p> <p>25</p>	<p style="text-align: right;">Page 157</p> <p>1 Hamilton-D was less than 8 or there was a 50 percent 01:48:18</p> <p>2 reduction in HAM-D or not or both. The depression</p> <p>3 alone from Hamilton-D at end-point. The K-SADS-L</p> <p>4 depression mood item alone at end-point, whether the</p> <p>5 CGI score was 1 or 2 at end-point versus 3 or 01:48:20</p> <p>6 higher. The K-SADS-L 9-item depression subscale,</p> <p>7 mean clinical global score and the mean Hamilton-D</p> <p>8 total Score.</p> <p>9 Q. Now, are the depression related variables,</p> <p>10 which are outlined in Table two also identified in 01:48:52</p> <p>11 the abstract which you coauthored and in the</p> <p>12 efficacy and safety evaluation section of that</p> <p>13 paper?</p> <p>14 A. I'm sorry. Let's see? Yes.</p> <p>15 Q. Now, does Table two set forth for any 01:49:26</p> <p>16 person who reads the article what the results were</p> <p>17 for the 8 depression related variables which you</p> <p>18 just described?</p> <p>19 A. Yes.</p> <p>20 Q. And are the statistical percentages 01:49:41</p> <p>21 revealed for anyone who reads the article, which you</p> <p>22 coauthored on the results of Study 329, to see how</p> <p>23 Paxil performed against a sugar pill or a placebo</p> <p>24 and whether or not Paxil performed better than the</p> <p>25 sugar pill? 01:49:50</p>

<p style="text-align: right;">Page 158</p> <p>1 MR. MURGATROYD: Objection; compound 01:50:09 2 question. 3 THE WITNESS: The statistics that are 4 provided in the table allow the reader a fair 5 comparison of the magnitude of the effect and 01:50:16 6 whether or not it was statistically significant 7 or not. 8 MR. DAVIS: Okay. Let's stop. 9 VIDEOGRAPHER: At this time we are going 10 off the record. The time is approximately 1:51 01:50:24 11 p.m. 12 (Recess taken.) 13 VIDEOGRAPHER: We are now back on the 14 record. The time is approximately 1:57 p.m. 15 This is the beginning of Tape 4, Day Two, of 01:56:35 16 the deposition of Dr. Ryan. Please proceed. 17 BY MR. DAVIS: 18 Q. Dr. Ryan, does Table two in the article 19 you coauthored on the results of Study 329 set forth 20 how Paxil performed on the two primary end-points? 01:56:48 21 A. Yes. 22 Q. Okay. And does it -- what does it say 23 about how Paxil performed on the two primary 24 end-points? 25 A. On the end-point of a Hamilton-D less than 01:57:11</p>	<p style="text-align: right;">Page 160</p> <p>1 A. By convention and by plan on this study as 01:58:39 2 you do on many studies we required a 0.5 to declare 3 something significant. The means -- and the P 4 values show you that there was a possibly, quote, 5 "trend" in that direction, but it's not at the level 01:58:58 6 you would declare significant, and so you have to 7 say we don't know whether they're better on those 8 measures or not. 9 Q. Now, does the table set forth and identify 10 how Paxil performed on the other depression related 01:59:11 11 variables, which were the secondary end-points? 12 A. Yes. 13 Q. And do you believe that the article, which 14 you coauthored on the results of Study 329 clearly 15 distinguishes between the efficacy results of the 01:59:20 16 primary and the secondary end-points? 17 A. Yes. 18 Q. Now, was there ever any attempt to hide or 19 confuse readers about what was a primary or 20 secondary end-point in the article which you 01:59:39 21 coauthored on the results of Study 329? 22 A. No. 23 Q. Now, was this article reviewed, analyzed 24 and commented on by multiple reviewers at the 25 journal where it was ultimately published? 01:59:48</p>
<p style="text-align: right;">Page 159</p> <p>1 8 and/or a 50 percent reduction in the baseline 01:57:13 2 HAM-D it shows that there was a 66.7 percent of the 3 people on paroxetine met the criteria of 55.2 4 percent. The ones on placebo met the criteria and 5 the P value was .11 so that was greater than .05 so 01:57:26 6 it was not significant on the HAM-D total score. 7 The mean on those treated on paroxetine was 18 -- 8 I'm sorry -- the mean post-treatment on those 9 treated with paroxetine was 18.24 compared with a 10 mean of 9 point -- I said that wrong -- let me try 01:57:52 11 it again. 12 Mean on paroxetine 8.24. Mean of those 13 treated on placebo 9.88. So the paroxetine -- the 14 difference on that was a P value of .13, which was 15 not significant. 01:58:05 16 Q. Does Table two show that Paxil did not 17 meet statistical significance on both of the primary 18 end-points? 19 A. Yes. 20 Q. Okay. And with respect to the P values 01:58:22 21 that you stated or set forth in Table two for the 22 two primary end-points, did they tell you anything 23 about whether there is a trend on whether or not 24 Paxil is or it is not effective in treating 25 adolescent depression? 01:58:37</p>	<p style="text-align: right;">Page 161</p> <p>1 A. Yes. 01:59:58 2 Q. And what's the process by which articles 3 like this go through a review before they're 4 published? 5 MR. MURGATROYD: Objection; calls for 02:00:01 6 speculation. 7 BY MR. DAVIS: 8 Q. Let me back up. Are you familiar with the 9 review process for articles which are submitted to 10 the Journal of the American Medical Academy 02:00:13 11 Association and the Journal for American Academy of 12 Child and Adolescent Psychiatry? 13 A. I have submitted articles to the Journal 14 of American Academy -- sorry -- I've submitted 15 articles to the American Academy Journal. I've been 02:00:31 16 a reviewer for them and I've been on their editorial 17 board. Yes. I'm familiar with the process. 18 Q. Based upon your time on their review 19 board, do you believe that the reviewers who are 20 asked to review articles at the Journal of the 02:00:52 21 American Academy of Child and Adolescent Psychiatry 22 have high standards in terms of the quality and the 23 clarity of the articles to be published in that 24 journal? 25 A. Yes. 02:01:07</p>

Page 162	Page 164
<p>1 Q. Okay. Was this article reviewed by 02:01:07 2 reviewers at the Journal of the American Academy of 3 Child and Adolescent Psychiatry?</p>	<p>1 sensitive to different changes in depression 02:03:35 2 between active compounds and placebo. 3 BY MR. DAVIS:</p>
<p>4 A. Yes. 5 Q. Okay. Do you believe the reviewers and 02:01:20 6 the editors of the Journal of the American Academy 7 of Child and Adolescent Psychiatry would have 8 allowed this article to be published if they 9 believed it would misinform readers about what was a 10 primary or a secondary end-point? 02:01:35</p>	<p>4 Q. And why were these four measures 5 determined to be of importance to evaluate and 02:03:58 6 analyze on that question? 7 A. Well, these four plus another couple 8 secondary ones, because they were capturing the 9 essence of the depression in different ways. They 10 were core of the essence of depression and they were 02:04:05 11 sort of -- they were questions that were known to be 12 assessed reliably by the instruments and they made 13 sense.</p>
<p>11 MR. MURGATROYD: Objection; lack of 12 foundation and it's compound. There's no 13 foundation that a reviewer can prevent an 14 article from being published.</p>	<p>14 Q. And what was it about the HAM-D Depressed 15 Item and the K-SADS-L mood item -- so the jury can 02:04:20 16 understands this -- so the jury can understand 17 this -- let me start my question again. So the jury 18 can understand this, what was it about the</p>
<p>15 THE WITNESS: No. I do not believe that 02:01:52 16 they would. 17 BY MR. DAVIS:</p>	<p>15 Item and the K-SADS-L mood item -- so the jury can 02:04:20 16 understands this -- so the jury can understand 17 this -- let me start my question again. So the jury 18 can understand this, what was it about the</p>
<p>18 Q. Let's talk just about the four secondary 19 end-points that showed that Paxil performed better 20 than sugar pill in Study 329. Keep the Table Two in 02:02:01 21 front of you there and also the article there.</p>	<p>19 Hamilton-D depressed mood item and K-SADS-L mood 20 item that helped you and the other clinical 02:04:29 21 investigators assess whether or not Paxil and 22 imipramine would or may perform better than a sugar 23 pill to treat depression?</p>
<p>22 What were the four secondary end-points 23 that were statistically significant and showed that 24 Paxil performed better than the sugar pill or 25 placebo? 02:02:18</p>	<p>24 A. Yes. The Hamilton scale that we used 25 contained 17 items. The K-SADS-L depression item 02:04:52</p>
Page 163	Page 165
<p>1 A. Sure. Hamilton-D score less than or equal 02:02:20 2 to 8 was the first. The second was the single item 3 about depressed mood from the Hamilton-D. The third 4 was the item about mood from the K-SADS-L mood 5 interview, and the last one was a clinical global 02:02:31 6 score of 1 or 2 at endpoint.</p>	<p>1 contained 9 items, and so they contained items that 02:04:52 2 go along with the syndrome of major depression and 3 we looked at them in aggregate, but we also thought 4 it would be informative to look simply at the 5 question of how depressed you are, because that's 02:05:11 6 the core symptom of major depressive disorder. 7 That's the criteria symptom to get in there and then 8 you're required to have so many other symptoms.</p>
<p>7 Q. And why did you and the other 8 investigators believe that these were important 9 secondary end-points to evaluate and assess in terms 10 of this study? 02:02:58</p>	<p>9 Q. How was it that the Hamilton-D less than 10 or equal to 8 was viewed as a core variable for 02:05:24 11 assessing whether or not Paxil and imipramine was 12 effective in treating adolescent depression?</p>
<p>11 MR. MURGATROYD: Objection; lack of 12 foundation.</p>	<p>13 A. The question we were trying to address 14 with that was, what fraction of the people get like 15 a whole lot better, get to the point where you say 02:05:41 16 they're not so bad. Not completely free of symptoms 17 perhaps, but really to the point where you say it's 18 subclinical, and that was that approximation for 19 that.</p>
<p>13 THE WITNESS: The problems that we faced 14 in designing this study was that there had been 15 no published studies of any antidepressant 02:03:07 16 agents in children or adolescents showing 17 efficacy at the time we designed this study. 18 Absolutely not.</p>	<p>15 a whole lot better, get to the point where you say 02:05:41 16 they're not so bad. Not completely free of symptoms 17 perhaps, but really to the point where you say it's 18 subclinical, and that was that approximation for 19 that.</p>
<p>19 All the tricyclics studies were negative 20 and Dr. Giles (phonetic) was underway and had 02:03:20 21 not been published so we had to go with very 22 little data -- with no data -- make good 23 choices on our primary outcomes measures, 24 clearly given that we had to say what are other 25 ways of measuring depression that might also be 02:03:35</p>	<p>20 Q. And why was the CGI or Clinical Global 02:06:01 21 Improvement score of 1 or 2 determined to be a core 22 variable in terms of assessing whether or not Paxil 23 or imipramine was effective in treating adolescents 24 depression? 25 A. Donald Klein at Columbia University and 02:06:14</p>

<p style="text-align: right;">Page 166</p> <p>1 others who are experts on adult depression had been 02:06:18 2 for sometime saying that Clinical Global 3 Improvement, which is a clinician's aggregate of 4 everything put together, using the clinician's 5 judgement unblinded was a really important thing to 02:06:26 6 look at in studies like this. A CGI of 1 or 2 would 7 be the kids where a clinician was saying these kids 8 are all better or almost all better. 9 Q. And just so the jury can understand, what 10 ends up getting categorized as a CGI score of 1 or 02:06:41 11 2? 12 A. That's much better or very much better. 13 Q. You told the Plaintiffs Counsel that it 14 would be wrong -- excuse me -- you told the 15 Plaintiffs Counsel that it would be wrong not to 02:07:09 16 look at the study -- strike that. I'm sorry. I'll 17 start again. 18 You told the Plaintiffs Counsel that it 19 would be wrong not to look at these core features of 20 efficacy. You also told him that it would be 02:07:22 21 unethical not to look at these core features for 22 assessing efficacy? Why do you believe that? 23 MR. MURGATROYD: Objection; compound 24 question. 25</p>	<p style="text-align: right;">Page 168</p> <p>1 of the data. You're saying that we're not going to 02:08:50 2 look at the rest of this data. We won't find out 3 more that's important to the world. 4 So in all of medicine there is the 5 question of how much to look at in addition to the 02:09:05 6 primary outcome measures to really understand the 7 deep questions about what -- we had an obligation to 8 say what's the best evidence that this does work or 9 doesn't work in addition to report that our primary 10 outcome measures didn't come out significant, 02:09:16 11 because, you know, the world has to -- you have to 12 treat these kids. You have a kid -- and without 13 really great data for how to treat them with a bad 14 disorder, and so simply saying we refuse to look at 15 anything more because the primary outcome measures 02:09:33 16 didn't come out better -- so we're not going to say, 17 did the other data look like it works and the other 18 data not look like it works is throwing away 19 critical information that the world needed. 20 Q. Let me ask you questions about the 02:09:48 21 K-SADS-L 9 item depression subscore and the mean 22 CGI. Did any of those show a statistically 23 significant improvement on Paxil or Imipramine? 24 A. The K-SADS-L 9 on depression subscore was 25 better on paroxetine than placebo. It did not reach 02:10:09</p>
<p style="text-align: right;">Page 167</p> <p>1 BY MR. DAVIS: 02:07:37 2 Q. I'll rephrase it. Do you believe it would 3 be wrong not to the look at those four efficacy 4 variables in the study? 5 A. Yes. 02:07:46 6 Q. Why do you believe that? 7 A. At the time the study was done and the 8 study was published we had a number of studies 9 showing the tricyclics -- we had the aggregate of 10 the studies on tricyclics and was enough to say that 02:08:01 11 they were unlikely to work very well, and we had no 12 studies showing they worked and we had -- when it 13 was published -- when it was designed we had 14 nothing, but when it was published we had one study 15 of the study of Dr. Emslie's, the first study of Dr. 02:08:13 16 Emslie finding efficacy for Prozac, for fluoxetine, 17 and this study then was the second study to provide 18 any control data for the world in the treatment of a 19 disorder associated with a lot of morbidity and 20 mortality, a lot of impairment and death and 02:08:31 21 suffering. 22 If you look only at the things that the 23 FDA -- for example, the primary outcomes as the FDA 24 would look at them for approval to say that this 25 compound is approved for that you are missing most 02:08:43</p>	<p style="text-align: right;">Page 169</p> <p>1 statistical significance. It had a P value of .07. 02:10:09 2 The CGI was better on paroxetine, but not at a 3 statistically significant level. It had a P value 4 of .09. 5 Q. And did that give you any information in 02:10:22 6 terms of a trend in either direction about whether 7 or not Paxil was effective in treating adolescent 8 depression? 9 A. Yes and no. It certainly said -- the good 10 things it said was the directionally was the same 02:10:35 11 and it sort of said it kind of came close to making 12 it. One can make a little of that. The thing I 13 think you can make something of it is the fact that 14 everything was in the same direction and it came 15 close. Alone, simply if you have something that 02:10:50 16 simply that reached your P value one doesn't want to 17 over interpret that single fact in isolation. I 18 think it's weak support, but probably a squidge of 19 support for the question of efficacy. 20 Q. But when you look at the trend for the 02:11:11 21 primary end-points and two of the secondary 22 end-points that don't meet statistical significance 23 and you match those up with the four end-points that 24 did meet statistical significance, do you interpret 25 that to mean that things were heading in the right 02:11:29</p>

Page 170	Page 172
<p>1 direction towards showing effectiveness of Paxil in 2 treating pediatric depression?</p>	<p>1 Q. Now, were those not core variables for 2 answering the question of whether or not Paxil is 3 effective in treating adolescent depression?</p>
<p>3 A. The fact that you had significance on core 4 items here that were planned, plus the other ones 5 all went in the same direction, yes, I think add 6 some support. 02:11:46</p>	<p>4 MR. MURGATROYD: Objection; assumes facts 5 not in evidence, lacks foundation. 02:15:07</p>
<p>7 Q. At the time of your findings on Study 329, 8 was it new information that was important to tell 9 clinicians who were faced with the difficult task of 10 treating adolescent depression? 02:12:07</p>	<p>6 THE WITNESS: We know that from prior 7 studies I collaborated with and studies that 8 others had done that during a depression 9 functioning deteriorates, as we've talked 10 about. We also know from studies -- that I 02:15:37 11 don't know if we've discussed so far -- that as 12 the clinical symptoms of depression improves 13 there is a lag in the improvement of the 14 psychosocial impairment.</p>
<p>11 A. I did this study to find out for 12 everybody, and my goal was to get this data out to 13 the field to everybody including clinicians.</p>	<p>15 When we designed the study we thought as 02:15:44 16 was -- there was a lot of excitement, 17 appropriately so, in adult studies for 18 depression at looking how people function in 19 their life, not just looking at how sad they 20 were. It was a topic of a lot of scientists 02:15:50 21 interest at the time and we felt it important 22 to include those in this study.</p>
<p>14 Q. Why did you want to get this information 15 out to everybody including clinicians? 02:12:37</p>	<p>23 We did not have prior studies to say, 24 which are the ones that are going to be the 25 most responsive to treatment so we had to pick, 02:16:05</p>
<p>16 A. Yes. Children and adolescents were being 17 treated with this compound and there was evidence 18 that this compound was helpful in adolescents, and 19 the only data on SSRIs at the time we published this 20 was the study by Dr. Emslie and that just was not 21 very much information for people to make decisions. 02:12:58</p>	<p>25 and we thought it was scientifically important. 02:16:13 26 It was clearly not the heart of interest, 27 was -- does it get the depression better, but 28 we thought this was an important question too.</p>
<p>22 Q. Let me turn your attention to page 766 of 23 the article that you coauthored on the results of 24 Study 329. If you could look at the column on the 25 right-hand side, can you tell whether there is a 02:13:28</p>	<p>29 My reading of how it turned out is that 02:16:24 30 we didn't show over the length of the study 31 that these things improved significantly more 32 with the Paxil than with the placebo. The fact 33 that they went in a good direction of slightly 34 more than the placebo is, I think, that one 02:16:43 35 can't interpret very much. It indicates you 36 may want to look at it in the future. It may 37 or may not indicate that they get better over 38 this period of time in terms of their 39 functioning. 02:16:44</p>
<p>Page 171</p>	<p>Page 173</p>
<p>1 discussion on whether or not Paxil separated 02:13:31 2 physically from the sugar pill, the non-symptom 3 measures of functioning, health and behavior?</p>	<p>4 BY MR. DAVIS: 5 Q. Are you aware of any other clinical 6 studies which were placebo controlled that assessed 7 depression and used either the Sickness Impact 8 Profile, the Autonomous Functioning Checklist, or 02:17:03 9 the Self-perception Profile as core variables in 10 assessing whether or not a medication was effective 11 in treating depression?</p>
<p>4 A. It says that "Although neither paroxetine 5 nor imipramine separated statistically from placebo 6 across the non-symptom measures of functioning, 7 health, and behaviors, improvements over baseline 8 were achieved for each active treatment group. 9 Placebo-treated subjects also improved along 10 behavior measures, but to a lesser extent." 02:13:48</p>	<p>12 A. In children I'm not aware of it. It could 13 be there. It's not something that I would 02:17:26</p>
<p>11 Q. Is this paragraph discussing quality of 12 life measures that had been assessed during Study 13 329?</p>	<p>14 A. That's correct. 02:14:46</p>
<p>14 A. Yes, it is. It's saying that the 15 directional comparisons were in the same direction. 16 That the kids on placebo directionally speaking did 17 worse, but that we did not achieve a statistically 18 significant difference.</p>	<p>20 Q. Are the quality of life measures that are 21 being assessed and being discussed there, are the 02:14:24 22 Sickness Impact Profile, the Autonomous Functioning 23 Checklist, and the Self-Perception Profile that's 24 described in the Efficacy and Safety Evaluation 25 section of the paper?</p>
<p>15 A. Yes, it is. It's saying that the 16 directional comparisons were in the same direction. 17 That the kids on placebo directionally speaking did 18 worse, but that we did not achieve a statistically 19 significant difference.</p>	<p>25</p>

<p style="text-align: right;">Page 174</p> <p>1 necessarily known had been one. 02:17:26</p> <p>2 Q. Have you ever been involved in a clinical</p> <p>3 trial involving pediatric patients where those three</p> <p>4 assessments were utilized either individually or in</p> <p>5 combination as core variables to assess whether or 02:17:37</p> <p>6 not a medication was effective in treating pediatric</p> <p>7 depression?</p> <p>8 A. No.</p> <p>9 Q. I'm handing you what was marked as</p> <p>10 Plaintiffs Exhibit 13. Just to refresh the jury's 02:18:16</p> <p>11 recollection, is this an e-mail that Dr. Michael</p> <p>12 Strober sent concerning some analyses on Study 329?</p> <p>13 A. Not precisely.</p> <p>14 Q. Can you tell the jury what that is,</p> <p>15 Doctor? 02:18:33</p> <p>16 A. Yes.</p> <p>17 MS. CONNELLY: Also I have an objection.</p> <p>18 I -- unless I'm wrong. This is not your</p> <p>19 document, is it?</p> <p>20 THE WITNESS: That's correct. It is not 02:18:39</p> <p>21 my document. This appears to be an e-mail from</p> <p>22 Mr. McCafferty to other GSK folks, Rosemary</p> <p>23 Oakes and William Bushnell, saying that</p> <p>24 Dr. Strober had suggested some things with what</p> <p>25 appears to be a cut and paste probably from 02:18:58</p>	<p style="text-align: right;">Page 176</p> <p>1 A. For two reasons. One, the second one is 02:20:26</p> <p>2 clearly talking about secondary analysis you would</p> <p>3 do if the primary one came out to sort of delineate</p> <p>4 it further, and the two of them are together so that</p> <p>5 makes it more likely the first one is also intended 02:20:33</p> <p>6 in that manner.</p> <p>7 The second reason is that cognitive</p> <p>8 disturbance, second -- motor slowing is very rare in</p> <p>9 children so it would not be a primary, it wouldn't</p> <p>10 be something that you would look at first, and 02:20:50</p> <p>11 Dr. Strober -- we had conversations about that -- it</p> <p>12 says very rare in children so you wouldn't look at</p> <p>13 that as a primary measure.</p> <p>14 Cognitive disturbance is also relatively</p> <p>15 rare in children with depression, and 02:21:05</p> <p>16 anxiety/somatization are symptoms of different</p> <p>17 though related disorders. So it wouldn't be a</p> <p>18 primary measure on a study of depression. It would</p> <p>19 be very interesting as secondary analysis.</p> <p>20 Q. When you say a secondary analysis, are you 02:21:24</p> <p>21 suggesting that it would be a core secondary</p> <p>22 variable to assess whether or not Paxil was</p> <p>23 effective in treating pediatric patients?</p> <p>24 A. No, I am not. I'm sorry that I used</p> <p>25 technical jargon. I'm suggesting that once you have 02:21:41</p>
<p style="text-align: right;">Page 175</p> <p>1 other e-mail of Dr. Strober's suggestions. 02:18:58</p> <p>2 BY MR. DAVIS:</p> <p>3 Q. What suggestions is Dr. Strober making</p> <p>4 concerning some analysis for Study 329?</p> <p>5 A. This e-mail suggests he's making the 02:19:11</p> <p>6 following: One, that the Hamilton-D four factor</p> <p>7 scores, which are composite scores of some, but not</p> <p>8 all of the questions assessing four different</p> <p>9 domains; anxiety/somatization, sleep, cognitive</p> <p>10 disturbance and psychomotor be analyzed, and then 02:19:24</p> <p>11 secondly if there is evidence for treatment effect</p> <p>12 to look at subgroups and the effect over time and</p> <p>13 time interactions showing different patterns of</p> <p>14 improvement across treatment.</p> <p>15 Q. Do you believe that those proposed 02:19:44</p> <p>16 analysis would be core variables for assessing</p> <p>17 whether or not Paxil or imipramine was effective in</p> <p>18 treating adolescents with depression?</p> <p>19 A. This, to me, looks like something that you</p> <p>20 would put in a secondary paper trying to explore 02:20:11</p> <p>21 stuff more.</p> <p>22 Q. And why do you believe those proposed</p> <p>23 analyses are not core or central to the question of</p> <p>24 whether or not Paxil or imipramine was effective in</p> <p>25 treating pediatric depression? 02:20:24</p>	<p style="text-align: right;">Page 177</p> <p>1 the main analysis of a study like this done you want 02:21:43</p> <p>2 to say, how much more information can you get from</p> <p>3 it to make hypothesis for future studies? So for</p> <p>4 example, you could do a lot of different comparisons</p> <p>5 without producing for multiple comparisons, because 02:21:59</p> <p>6 you want to say what's all the things that are</p> <p>7 different here and then make specific hypothesis on</p> <p>8 your next study. That's what I'm suggesting that</p> <p>9 would be appropriate for.</p> <p>10 Q. Let me turn your attention to the 02:22:11</p> <p>11 conclusion section of the article that you</p> <p>12 coauthored on the results of Study 329.</p> <p>13 I'm going to ask you to read the very</p> <p>14 first sentence under the conclusion section for us.</p> <p>15 A. "The findings of the study provide 02:22:26</p> <p>16 evidence of the efficacy and safety of the SSRI,</p> <p>17 paroxetine, in the treatment of adolescent</p> <p>18 depression."</p> <p>19 Q. Do you believe that to be a true</p> <p>20 statement? 02:22:41</p> <p>21 A. I believe that to be a true statement.</p> <p>22 (Defendants Deposition Exhibit No. 8</p> <p>23 was marked for identification.)</p> <p>24 Q. Now, do you believe -- what I've marked as</p> <p>25 Defendants Exhibit 8 a fair and accurate 02:22:46</p>

Page 178	Page 180
<p>1 representation of the statement that you read to the jury concerning the conclusion? What was in the conclusion in the study you coauthored?</p>	<p>1 paroxetine, in the treatment of adolescent depression?</p>
<p>2 A. Yes.</p>	<p>2 A. Yes.</p>
<p>3 Q. Okay. Now, do you believe that the -- excuse me -- do you believe that the article that you coauthored on the results of Study 329 properly describe and disclose the efficacy results of that study?</p>	<p>3 MR. MURGATROYD: Objection; one, it's leading; two, it misstates the evidence.</p> <p>4 BY MR. DAVIS:</p> <p>5 Q. Okay. Well, just to fix that. What did you say -- again, Dr. Ryan, what did you say in the conclusion section?</p>
<p>6 A. Yes. 02:23:05</p>	<p>6 MR. MURGATROYD: Objection; asked and answered. You already done that.</p>
<p>7 Q. And at any time did any GlaxoSmithKline employee try to influence you on how you should interpret the efficacy results on Study 329?</p>	<p>7 MS. CONNELLY: You can answer.</p> <p>8 THE WITNESS: We said the findings of this study provide evidence of the efficacy and safety of the SSRI, paroxetine, in the treatment of adolescents depression. We said it that way because a single study no matter how positive doesn't mean conclusively. Science to man's replication.</p>
<p>9 A. Not to my memory. 02:23:22</p>	<p>9 BY MR. DAVIS: 02:26:22</p>
<p>10 Q. Do you believe that you would recall something like that if some GlaxoSmithKline employee was trying to improperly influence you in terms of how the data should be presented in this article?</p>	<p>10 Q. And do you believe that's a general known principle in the scientific field?</p> <p>11 A. Yes.</p> <p>12 Q. Do you believe that other physicians who treat psychiatric disorders understand that</p>
<p>11 A. Yes. 02:23:33</p>	<p>11 02:26:31</p>
<p>12 Q. Now, in terms of -- if this study had been funded -- strike that.</p>	<p>12 BY MR. DAVIS: 02:26:48</p>
<p>13 Have you conducted studies for the National Institute of Mental Health?</p>	<p>13 Q. And do you believe that's a general known principle in the scientific field?</p>
<p>14 A. Yes. 02:23:41</p>	<p>14 A. Yes.</p>
<p>15 Q. What is the National Institute of Mental Health?</p>	<p>15 Q. Do you believe that other physicians who treat psychiatric disorders understand that</p>
<p>16 A. The National Institute of Mental Health is one of approximately 20 institutes under the National Institute of Health. It funds the large majority of medical research in this country. 02:24:20</p>	<p>16 02:26:59</p>
<p>17 Q. How many studies have you conducted from funding from the National Institute of Mental Health?</p>	<p>17 principle? 02:27:07</p>
<p>18 A. I don't know. A number. I've been PI on, principle investigator, on six, seven maybe and co-investigator on a larger number than that. 02:24:33</p>	<p>18 A. Yes.</p>
<p>19 Q. If this study had been funded by the National Institute of Mental Health, would you have described the efficacy and safety findings of the study in the exact same way that you reported in the article that was published?</p>	<p>19 Q. Do your conclusion there say other medications prove to be more efficacious in treating children and adolescents? 02:27:37</p>
<p>20 A. Yes. 02:25:03</p>	<p>20 A. No.</p>
<p>21 Q. Now, in the conclusion section of the article that you coauthored of the results of Study 329, did you state that it had been conclusively established that paroxetine or Paxil is effective in treating adolescent depression?</p>	<p>21 MR. MURGATROYD: Objection; calls for speculation.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. To your knowledge, are there any other medications that have proven to be more efficacious than SSRIs in treating depression in children and adolescents? 02:27:46</p>
<p>22 A. Yes. 02:25:03</p>	<p>22 MR. MURGATROYD: Objection; calls for speculation.</p>
<p>23 Q. Did you instead say this study provided evidence of the efficacy and safety of the SSRI,</p>	<p>23 BY MR. DAVIS:</p> <p>24 Q. Sorry?</p> <p>25 A. No.</p> <p>26 Q. Do you recall whether there were any letters to the editor that were about the conclusions that you and the other coauthors reached about the efficacy results in Study 329?</p>
<p>24 A. I do not believe that we did. 02:26:03</p>	<p>24 A. I believe there was four published letters to the editor with three responses. My colleagues 02:28:05</p>
<p>25 Health? 02:24:11</p>	<p>25 02:27:07</p>

	Page 182		Page 184
1 and I would not necessarily have seen letters sent 2 to the editor that the editor did not ask us to 3 comment on.	02:28:07	1 time of his writing this letter was in the	02:30:59
4 (Defendants Deposition Exhibit No. 9 5 was marked for identification.)	02:47:32	6 BY MR. DAVIS:	2 department -- he's a B.M. Ph.D in the department of 3 psychological medicine, Women's and Children 4 Hospital, Department of philosophy, Finders 5 University, Adelaide, Australia. Dr. Tonkin is a
6 BY MR. DAVIS:		7 Q. Okay. Doctor, I'm going to hand you	6 B.M. Ph.D in the department of clinical and 7 experimental pharmacology, University of Adelaide, 8 Royal Adelaide Hospital, Adelaide, Australia,
8 what's been marked as Defendants Exhibit 9 and ask 9 you if that is one of the letters that were sent		10 into the Journal of the American Academy of Child	9 Q. So those are letters that had come in from 10 two individuals in Australia? 02:31:28
11 and Adolescent Psychiatry about the efficacy results 12 of Study 329 as well as the reply by you and other	02:28:39	13 coauthors?	11 A. That's correct.
14 A. Yes.		15 Q. Did you draft this reply letter?	12 Q. And did you agree with the comments that 13 Dr. Jureidini and Dr. Tonkin sent in concerning the 14 article that you and others coauthored about the 15 results of Study 329? 02:31:44
16 Q. Did you draft this reply letter?	02:29:07	17 A. I made the first draft on this reply 18 letter.	16 A. No. 17 MR. MURGATROYD: Objection; vague and 18 ambiguous.
19 (Defendants Deposition Exhibit No. 10 20 was marked for identification.)		21 Q. Okay. I'm going to hand you what's been	19 BY MR. DAVIS:
22 marked as Exhibit 10 and ask you if that is a copy 23 of the first draft of this reply letter that you	02:29:18	24 prepared and circulated to other coauthors?	20 Q. Why don't we for the jury's benefit, could 21 you read the second paragraph to the reply letter 22 and I'll stop you when I have a question?
25 A. This is e-mail from me to Dr. Keller, Ms. Laden, Dr. Strober, Mr. McCafferty, and it says	02:29:48		23 A. In my draft or the final published reply? 24 Q. The final published reply.
			25 A. "It seems that they argue that (1) we were 02:32:14
	Page 183		Page 185
1 Draft 01. It's from my files. I assume that it's 2 the first draft from what it says.	02:30:01	3 MR. MURGATROYD: What Exhibit number is 4 this?	1 insufficiently clear in distinguishing between our 2 primary and secondary outcome measures and (2) our 3 assessment that this study found paroxetine 4 effective is incorrect. We feel that we were quite 5 clear about which were primary outcome measures and 6 which were secondary; this is explicitly and clearly 7 elucidated in the abstract of the article; Moreover, 8 the manuscript explicitly addressed the various 9 limitations of the study design and discussed in 10 detail these limitations with regard to the clinical 11 implications of the research results. Within this 12 context, because our two outcome measures did not 13 reach a P level of less than .05 level of 14 statistical significance, the more complex question 15 that remains is whether or not we fairly interpreted 16 the pattern of significant P values across the range 17 of secondary endpoints as indicating that paroxetine 18 is better than placebo for treating adolescent 19 depression."
5 MR. DAVIS: Ten.	02:30:14	6 MR. MURGATROYD: And it's an authentic 7 document?	20 Q. Let me stop you there. Dr. Ryan, what was 21 the date which you coauthored on the results of 22 Study 329 was published? What was the publication 23 date?
8 THE WITNESS: As far as I can tell, yes.		9 BY MR. DAVIS:	24 A. The publication date on the Keller et. al, 25 article was July 2001. 02:33:20
10 Q. What is the date of the e-mail that you 11 sent circulating the draft 1?	02:30:22	12 A. November 6, 2002.	02:32:14
13 Q. Okay. And which physicians were you 14 replying to in this that had sent in a letter to the		15 Journal of the American Academy of Child and 16 Adolescent Psychiatry?	02:32:24
17 A. This is in reply to the Jureidini and 18 Tonkin letter.		19 Q. And where are Dr. Jureidini and Dr. Tonkin 20 located?	02:32:58
21 A. I believe they're in Europe, but I don't 22 remember more detail than that.		23 Q. Could you look on the first page where 24 it's marked on Exhibit 9?	02:32:58
25 A. I could. I'm sorry. Dr. Jureidini at the	02:30:52		

Page 186		Page 188			
1	Q. And what's the date of when the letter and the reply letter from you and the coauthors?	02:33:35	1 (HAM-D) in adolescent treatment studies and has gone virtually uniformly to using the Children's Depression Rating Scale-Revised because the latter better and more reliably captures aspects of depression in youth. Surely a national regulatory body charged with approving or not approving a medication for a particular use might well simply say that if a study does not show efficacy on the primary endpoint(s), it is a failed study and secondary outcome measures cannot then be used for approval. However, as scientists and clinicians we must adjudge whether or not the study overall found evidence of efficacy, and we didn't have the convenience of falling back on such a simple rule. If we choose wrongly (in whichever direction), we don't treat depressed children as well as the data would permit. Because we found a clear pattern of significant P values across multiple secondary analyses (recovery is assessed by the HAM-D less than 8, HAM-D depressed mood item, the scheduled -- Q. Let me stop you there. You say: If we choose wrongly in whichever direction we don't treat depressed children as well as the data would permit. Why did you believe that?	02:36:07	02:36:16
2	MR. MURGATROYD: Object; compound question.				
3	THE WITNESS: The date appears to be May 2003.	02:33:43			
4	BY MR. DAVIS:				
5	Q. Is that the date that the letter from Dr. Jureidini and Tonkin and the reply letter that you and the other coauthors sent was published?	02:33:50			
6	A. Was published? That's correct.				
7	Q. It was published in the same journal where the Keller et. al, article was published?				
8	A. Yes.				
9	Q. All right. You read a section of the reply letter. Do you believe that to be a truthful and accurate statement?	02:34:20			
10	A. Yes.				
11	Q. Why did you write that, "The more complex question that remains is whether or not we fairly interpreted the pattern of significant P values across the range of secondary endpoints as indicating that paroxetine is better than placebo for treating adolescent depression"?	02:34:37			
12	A. Yes. Again, if we had simply stopped with	02:34:48			
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Page 187		Page 189			
1	the primary outcome measures we would have said that that's -- we refuse to look more at this even though there's -- there's no other data in the world right now to help us answer this question and we're simply going to say the primary outcome measures were sort of in the right direction, didn't reach statistical significance, and we're not going to find out anything more to see if we can help children or to find out where the science lies or the truth lies.	02:34:52	1 looked only at this and it doesn't work we discourage use. If it truly does work and we simply fail to find it on our two primary outcome measures and we discourage use that's a bad thing. If -- in the either direction part is if we get too excited about parts of it and say this compound works and it turns out in subsequent studies it doesn't we also encourage more use that otherwise they should have been treated with different things. So both ways of -- we had limited data. We had to -- you know, you have to say what does the data say, and both ways of being wrong are wrong and have disadvantageous.	02:37:20	02:37:22
2	As one would, I think essentially always do, we tried to say how do you find out more of the truth in this matter, and we looked at what seemed to be useful to find that out and published it.	02:35:05			
3	Q. Okay. Now, if you could read the second paragraph. I'll stop you when I have a question.	02:35:14			
4	A. "This study was designed at a time when there was no randomized control trials showing antidepressant (tricyclic antidepressant or SSRI) superiority to placebo, so we had no prior data from which to astutely pick our outcome measures."	02:35:35			
5	Q. And that's a true statement?				
6	A. Yes.				
7	Q. Go ahead.				
8	A. "The field has moved strongly away from using the Hamilton Rating Scale for depression,	02:35:43			
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<p style="text-align: right;">Page 190</p> <p>1 body in charge with approving or not approving a 02:38:33 2 medication for a particular use might well simply 3 say that if a study does not show efficacy on the 4 primary endpoints it is a failed study, and I'm 5 asking you, do you believe that was the right way to 02:38:48 6 go with respect to Study 329. 7 A. I believe that the FDA does a good job and 8 that sort of rule has served it well, because it is 9 accomplishing one task. I believe it's not the only 10 thing you want to do on a study like -- which is the 02:39:09 11 first one, because you're trying to bring all the 12 juice from it that you have either in favor or 13 against, not simply say, does it reach FDA 14 regulatory requirements. 15 Q. The last sentence of that paragraph reads 02:39:18 16 that "Without established reliable measures that 17 distinguish medication responders from nonresponders 18 at the time the study was designed, it is not 19 surprising that the primary measures did not reach 20 significance while other measures did." 02:39:35 21 What are you trying to explain in that 22 sentence? 23 A. Right. I'm trying to say that a very 24 reasonable and even likely hypothesis as we picked 25 was okay, but not great measures and so we found 02:39:52</p>	<p style="text-align: right;">Page 192</p> <p>1 placebo response rates. That's not unique to 02:40:59 2 pediatric studies or adolescent studies; however, a 3 number of adult studies also show that. 4 Q. In terms of the pediatric studies that 5 have been done on SSRIs which have showed a high 02:41:07 6 placebo response rate, what do you take away from 7 that in terms of trying to assess what the 8 difficulty is in conducting studies? 9 A. I take away two separate things. One of 10 which is that children seem to get better to a 02:41:09 11 greater rate than adults for at least a while just 12 from all the encouraging parts of treatment, just 13 from the nonspecific good stuff of coming in and 14 meeting with somebody nice and expecting to get 15 better and getting more attention and so forth. 02:41:11 16 That's part of all treatments in medicine, but in 17 some disorders that's sort of a larger impedance. 18 It's larger pushed towards getting better than for 19 other disorders and there's considerable anecdotal 20 and a little bit of clinical data that children sort 02:41:11 21 of get more of that than adults do. 22 The second thing is that it may also 23 indicate instruments that aren't as specific as you 24 like, assessment instruments. 25 Q. Assessment instruments for determining 02:42:11</p>
<p style="text-align: right;">Page 191</p> <p>1 less of an indication for efficacy than we would had 02:39:59 2 we picked better measures. 3 Q. Was there a high placebo response rate for 4 Study 329? 5 A. There was a relatively high placebo 02:40:09 6 response rate. 7 Q. What does that tell you about trying to 8 assess efficacy in Study 329? 9 MR. MURGATROYD: Objection; leading. 10 THE WITNESS: A number of studies. 02:40:16 11 MR. DAVIS: Let me back up. Let me 12 respond to the objection. 13 BY MR. DAVIS: 14 Q. Does the fact that there was a high 15 placebo response rate tell you anything in terms of 02:40:28 16 trying to assess efficacy in Study 329? 17 A. A high placebo response rate 18 mathematically makes it much harder to find efficacy 19 from a mathematical statistical standpoint even if 20 it's there. 02:40:39 21 Q. And in terms of studies that have been 22 done in pediatric patients with SSRIs, have there 23 been other studies which have shown a high placebo 24 response rate? 25 A. A number of the studies have had high 02:40:58</p>	<p style="text-align: right;">Page 193</p> <p>1 whether or not a medication is effective in treating 02:42:11 2 the pediatric population? 3 A. For determining whether or not the 4 depression is improved, yes. 5 Q. Okay. And in terms of the reply letter 02:42:18 6 that you coauthored to Drs. Jureidini and Tonkin's 7 letter, do you stand by the statements that you made 8 in that letter? 9 A. Yes. 10 (Defendants Deposition Exhibit No. 11 02:42:37 11 was marked for identification.) 12 Q. Okay. I'm going to hand you what has been 13 marked as Exhibit 11 and ask you if you could look 14 through that document and recognize it as a summary 15 of the reviewer comments that came in from the 02:44:22 16 Journal of the American Medical Association about 17 the draft manuscript on the results of Study 329? 18 A. That is certainly what that appears to be. 19 I don't have any way of authenticating it 20 separately. 02:44:48 21 Q. What I want to do is turn your attention 22 to reviewer's No. 2 comments, and can you read -- do 23 you remember receiving comments back from the 24 Journal of the American Medical Association? 25 A. Not before -- no, I do not remember the 02:45:13</p>

<p style="text-align: right;">Page 194</p> <p>1 details on these or anything about them. 02:45:14</p> <p>2 Q. Okay.</p> <p>3 A. I do remember that after discussions</p> <p>4 yesterday that we submitted several places,</p> <p>5 including first in the Journal of American Medical 02:45:22</p> <p>6 Association, otherwise, no, I don't remember the</p> <p>7 details of that.</p> <p>8 Q. Let me turn your attention to --</p> <p>9 Plaintiffs have asserted that the authors of -- you</p> <p>10 know, the authors of this -- of the -- of the Keller 02:45:31</p> <p>11 et. al, article -- this interpreted an overstatement</p> <p>12 in their results of Study 329, and I want to walk</p> <p>13 you through some of the comments that the reviewers</p> <p>14 made about those results. Okay? If you can turn to</p> <p>15 Reviewer's No. 2 comment. 02:45:48</p> <p>16 MR. MURGATROYD: First of all, let me</p> <p>17 object if you are going to cherry pick the</p> <p>18 reviewer's comments that it's -- you are using</p> <p>19 the partial document and not a complete</p> <p>20 document, therefore, it's inadmissible. 02:46:05</p> <p>21 MR. DAVIS: You can ask the doctor</p> <p>22 whatever question you like and show him any</p> <p>23 document you like.</p> <p>24 BY MR. DAVIS:</p> <p>25 Q. Look at Reviewer's No. 2 comments. Do you 02:46:11</p>	<p style="text-align: right;">Page 196</p> <p>1 A. It appears to be as you represent it, 02:47:52</p> <p>2 certainly it's on their letterhead and Dr. Dulcan</p> <p>3 who signed it was the editor then. I can't</p> <p>4 separately authentic it.</p> <p>5 Q. And can you turn to the second of the last 02:48:16</p> <p>6 page, Dr. Ryan?</p> <p>7 A. Yes.</p> <p>8 Q. And if you could just read to yourself the</p> <p>9 second paragraph and let me know when you're done?</p> <p>10 A. I am done. 02:48:28</p> <p>11 Q. Do you recall -- let me strike that.</p> <p>12 Did you get feed -- did you and other</p> <p>13 authors get feedback from the editor of the American</p> <p>14 Academy of Child and Adolescent Psychiatry of what</p> <p>15 they believe to be the merits of the study? 02:48:44</p> <p>16 A. Reviewers are encouraged to include the</p> <p>17 strengths of the paper to help the editor judge the</p> <p>18 importance of the paper. Sometimes they do.</p> <p>19 Sometimes they do not. It appears that they did in</p> <p>20 this case. 02:49:07</p> <p>21 Q. What feedback did you and the other</p> <p>22 coauthors get about the strengths of this study and</p> <p>23 reflected in this document?</p> <p>24 A. I only had time to read the one paragraph.</p> <p>25 That's clearly a feedback about the strengths. I do 02:49:14</p>
<p style="text-align: right;">Page 195</p> <p>1 see -- if you could, could you read the second -- 02:46:11</p> <p>2 first sentence in the second paragraph?</p> <p>3 A. "The strength of the study is that it is</p> <p>4 the first replication of the efficacy of</p> <p>5 antidepressants in treatment of adolescent 02:46:18</p> <p>6 depression and the first report of efficacy of</p> <p>7 paroxetine."</p> <p>8 Q. Okay. And could you read the second</p> <p>9 sentence please?</p> <p>10 A. "The introduction does an excellent job of 02:46:29</p> <p>11 discussing the past studies of adolescent depression</p> <p>12 and in describing the limitations of all but one of</p> <p>13 those studies."</p> <p>14 Q. All right. And do you believe that the</p> <p>15 strength of this study is it's the first replication 02:46:41</p> <p>16 of evidence of efficacy of antidepressants in the</p> <p>17 treatment of adolescent depression?</p> <p>18 A. Yes.</p> <p>19 (Defendants Deposition Exhibit No. 12</p> <p>20 was marked for identification.) 02:47:24</p> <p>21 Q. I'm going to hand you what's been marked</p> <p>22 as Defendants Exhibit 12 and ask you if you</p> <p>23 recognize this as the reviewer's comments that came</p> <p>24 back from the Journal of the American Academy of</p> <p>25 Child and Adolescent Psychiatry? 02:47:46</p>	<p style="text-align: right;">Page 197</p> <p>1 not know on the rest of this, because I do not 02:49:14</p> <p>2 remember it.</p> <p>3 Q. Okay. Well, if you could read what that</p> <p>4 second paragraph reads.</p> <p>5 MR. MURGATROYD: I need to object. Again, 02:49:24</p> <p>6 that if you are going to read the document --</p> <p>7 well -- go ahead read it.</p> <p>8 THE WITNESS: "This study has multiple</p> <p>9 strengths, including large sample size, 02:49:31</p> <p>10 randomized controlled design, and the use of</p> <p>11 standardized measures addressing multiple</p> <p>12 domains. Moreover, the study addresses an</p> <p>13 important area of clinical child psychiatry,</p> <p>14 the efficacy of antidepressant therapy in</p> <p>15 depressed youth. The results are clearly 02:49:43</p> <p>16 presented. Documenting that paroxetine has</p> <p>17 efficacy in adolescent depression is an</p> <p>18 important finding."</p> <p>19 BY MR. DAVIS:</p> <p>20 Q. Does this reviewer's comments suggest 02:49:58</p> <p>21 anything that the efficacy results were somehow</p> <p>22 hidden or not clearly set forth in the manuscript</p> <p>23 that was submitted?</p> <p>24 A. No. This reviewers comments in its</p> <p>25 entirety -- this reviewer in the entirety in the 02:50:18</p>

Page 198	Page 200
1 feedback does not suggest that. 02:50:18	1 Q. And in that first full paragraph, is there 02:53:26
2 Q. Now, you testified that earlier that there 3 was a meeting in November of 1997 of the clinical 4 investigators and GSK employees to discuss the 5 results of Study 329; is that right? 02:50:48	2 a description about what is meant by the term 3 emotional lability?
6 A. Yes.	4 A. There is an example of some of the things 5 that were included under emotional lability, yes. 02:53:43
7 Q. And at that meeting, do you recall who was 8 present?	6 Q. Will you tell the jury what is described 7 there in terms of examples of emotional lability?
9 A. There were maybe 20. I would estimate 10 that there was about 25 people present to the best 11 of my memory. All of the PIs of the site were 12 there. Dr. Birmaher from the Pittsburgh site was 13 there. There were a number of GSK or SKB people 14 there. I do not remember all who was there. 02:51:03	8 A. Suicide with ideation/gestures. 9 Q. Okay.
15 Q. Do you remember whether or not Mr. 16 McCafferty was there? 02:51:24	10 A. Conduct problems or hostility. 02:54:01
17 A. Mr. McCafferty was there.	11 Q. Let me stop you there. The example of 12 emotional lability is --
18 Q. Do you remember whether or not Dr. Ivan 19 Gergel was present?	13 A. You're right. I misread that.
20 A. I believe he was. I'm not certain. 02:51:43	14 Q. Could you read that again? 15 A. So they have emotional lability and they 16 give the example; suicidal ideation/gestures. 02:54:01
21 Q. Do you remember the names of any of the 22 GlaxoSmithKline employees that --	17 Q. Okay. And then does the paper then report 18 within the descriptive term of emotional lability 19 that it does include suicidal ideation or gestures?
23 A. No. I apologize. I do not.	20 A. Yes. 02:54:20
24 Q. Now, were there efficacy findings of Study 25 329 discussed at this November 1997 meeting? 02:51:58	21 Q. And is there also a discussion of adverse 22 events in Table three on the proceeding page which 23 also discusses the adverse events which fell under 24 the term of emotional lability? 25 A. Table three includes the numbers and 02:54:46
Page 199	Page 201
1 A. Yes. 02:52:03	1 percentages and the three different treatment arms 2 that experienced emotional lability, yes. 02:54:46
2 Q. And were the adverse events discussed at 3 this November 1997 meeting?	3 Q. Okay. And in the article itself, do you 4 and the other authors discuss an assessment of what 5 was believed to be occurring with the patients with 6 the adverse events? 02:55:05
4 A. Yes.	7 A. To some extreme, yes.
5 Q. Did those adverse events include adverse 6 events of suicidal thoughts or behaviors and conduct 7 disorders? 02:52:07	8 Q. Now, was there also ... 9 VIDEOGRAPHER: We need to change tapes in 10 two minutes. 02:56:14
8 A. Yes.	11 MR. DAVIS: Let's go ahead and change the 12 tape.
9 Q. Based on the data that you saw then, was 10 there a statistically significant and increased risk 11 of suicidal thoughts and behaviors in the adolescent 12 patients taking Paxil compared to those taking the 13 sugar pill or placebo? 02:52:18	13 VIDEOGRAPHER: At this time we're going 14 off the record at 2:57 p.m to change 15 videotapes. This is the end of Tape Number 4. 02:56:18
14 A. No.	16 (Recess taken.)
15 Q. Did you and the other authors discuss 16 adverse events in the published article about the 17 results of Study 329? 02:52:37	17 VIDEOGRAPHER: This is the beginning of 18 the videotape of Dr. Ryan. The time is 3:04 19 p.m. Tape 5. Please proceed. 20 (Ryan Defendant's Deposition Exhibit 02:47:32
18 A. Yes.	21 No. 13 was marked for identification.)
19 Q. Okay. Let's talk about those. Looking on 20 page 769 is there a discussion there about the 21 serious adverse events that were discussed in the 22 published article on Study 329? 02:53:01	22 BY MR. DAVIS:
23 A. On the top of 769?	23 Q. Dr. Ryan, I'm going to hand you what's 24 been marked as Defendants No. 13, and it's got 25 underline on it by -- that I'm going to need to 03:02:59
24 Q. Yes.	
25 A. The first full paragraph? 02:53:22	

	Page 202		Page 204
<p>1 substitute out. That's not probably the original 03:02:59</p> <p>2 letter, but I'm going to ask you, is Defendants</p> <p>3 Exhibit 13 a copy of a reply that was sent to the</p> <p>4 Journal of the American Academy Child and Adolescent</p> <p>5 Psychiatry which was published in April of 2002? 03:03:13</p> <p>6 A. It's a copy of a letter to the editor from</p> <p>7 Mitch Parsons of Alberta, Canada. A letter to the</p> <p>8 editor about our -- the Keller et. al, letter and</p> <p>9 the response of Dr. Keller and myself to that</p> <p>10 letter. 03:03:31</p> <p>11 Q. And are these series of articles</p> <p>12 discussing adverse events that were reported in the</p> <p>13 Keller article including those that -- concerning</p> <p>14 emotional lability?</p> <p>15 A. Yes. 03:03:48</p> <p>16 Q. All right. And who are the -- in terms of</p> <p>17 the reply letter back to Dr. Parsons, who was the</p> <p>18 individuals who responded?</p> <p>19 A. The authors of the reply letter were Dr.</p> <p>20 Keller, myself and Dr. Wagner. 03:04:05</p> <p>21 Q. And do you remember assisting in the</p> <p>22 preparation of this reply letter?</p> <p>23 A. Yes.</p> <p>24 Q. And did you have input into the content?</p> <p>25 A. Yes. 03:04:20</p>	<p>1 A. The rest of the paragraph? 03:05:26</p> <p>2 Q. Yes, sir.</p> <p>3 A. "Acute psychosocial stressors, for example</p> <p>4 arguments with boyfriend and parents, torment by</p> <p>5 peers, medication non-compliance, and/or untreated 03:05:31</p> <p>6 Comolli disorders. For example conduct disorder</p> <p>7 were judged by the investigators to account for the</p> <p>8 adverse effects in all 10 patients. Only headache</p> <p>9 in the one patient was judged to be related</p> <p>10 paroxetine." 03:05:46</p> <p>11 Q. When the authors of the Keller's et. al,</p> <p>12 article received the letter from Dr. Parsons</p> <p>13 concerning his questions about adverse events, did</p> <p>14 the clinical investigators involved in Study 329</p> <p>15 discuss the adverse events that he had questions 03:06:13</p> <p>16 about?</p> <p>17 A. Yes.</p> <p>18 Q. All right. Can you tell me about what was</p> <p>19 done?</p> <p>20 A. I don't remember the details. Dr. Keller 03:06:20</p> <p>21 took the lead on this one. As I remember it as best</p> <p>22 I can we looked at the available data, the clinical</p> <p>23 data around that time to see what more was</p> <p>24 documented.</p> <p>25 Q. And do you remember what it is in terms of 03:06:31</p>		
<p>1 Q. Can you read the first two sentences of 03:04:20</p> <p>2 the reply letter, please?</p> <p>3 A. "We thank Drs. Parsons and Weintrob for</p> <p>4 their words of encouragement and for their questions</p> <p>5 about adverse effects associated with paroxetine in 03:04:28</p> <p>6 our study of adolescents with major depression</p> <p>7 (Keller et al., 2001). In particular, Dr. Parsons</p> <p>8 was interested in our decision-making process for</p> <p>9 determining that adverse effects in the paroxetine</p> <p>10 treated group were not attributable to the selective 03:04:28</p> <p>11 Serotonin Reuptake Inhibitor."</p> <p>12 Q. And can you also read the next sentence,</p> <p>13 please?</p> <p>14 A. "In the 11 paroxetine-treated patients</p> <p>15 with serious adverse effects, 1 experienced headache 03:05:01</p> <p>16 and 10 experienced psychiatric symptoms, including</p> <p>17 emotional lability, suicidal ideation, conduct</p> <p>18 problems and behavioral disturbance."</p> <p>19 Q. And can you read the next sentence,</p> <p>20 please? 03:05:14</p> <p>21 A. "The psychiatric symptoms were</p> <p>22 chronologically related to a variety of situational</p> <p>23 factors."</p> <p>24 Q. And can you please read the last --</p> <p>25 through that paragraph? 03:05:24</p>	<p>1 available clinical data that you looked at? 03:06:31</p> <p>2 A. No.</p> <p>3 Q. And did you -- you and the other clinical</p> <p>4 investigators coordinate with GlaxoSmithKline to</p> <p>5 look at analysis in this data about the adverse 03:06:46</p> <p>6 events?</p> <p>7 A. We coordinated with GlaxoSmithKline to</p> <p>8 look at the data. I don't think -- this was not a</p> <p>9 statistical analysis. It was not a, you know,</p> <p>10 lining them up and saying what's most likely one by 03:07:07</p> <p>11 one on this by simply looking at the descriptions.</p> <p>12 Q. And when you say descriptions, are you</p> <p>13 describing case report narrative?</p> <p>14 A. That's correct. That's what I should have</p> <p>15 said. 03:07:22</p> <p>16 Q. And for the jury's benefit, what's a case</p> <p>17 report narrative?</p> <p>18 A. As the research subjects -- as the</p> <p>19 adolescents with MDD would come in and they would</p> <p>20 have an adverse event there was a free text 03:07:22</p> <p>21 narrative written describing the adverse event.</p> <p>22 Q. Let me hand you what's been marked as</p> <p>23 Plaintiffs Exhibit 33. Doctor, is that a copy of</p> <p>24 the paper that was coauthored by Dr. Alan Apter and</p> <p>25 others and is entitled "Evaluation of Suicidal 03:07:46</p>		

Page 206	Page 208
<p>1 Thoughts and Behaviors in Children and Adolescents 03:07:46 2 taking Paroxetine"?</p> <p>3 A. Yes.</p> <p>4 Q. Did you assist in the analysis of the 5 adverse events described in this study by doing a 03:08:09 6 blinded review?</p> <p>7 A. Yes.</p> <p>8 Q. And let's turn to the -- did this analysis 9 include additional adverse effects in Study 329 that 10 might be possible suicidal thoughts or behaviors 03:08:35 11 experienced by the adolescent patients in Study 329?</p> <p>12 A. Yes.</p> <p>13 Q. Look at Table Five that appears on page 14 85, Doctor.</p> <p>15 A. I have it in front of me. 03:08:58</p> <p>16 Q. What's the title of that table?</p> <p>17 A. Incidence Density for Self Harm by 18 Treatment Group and Indication For On-Therapy plus 19 30 Days Post Treatment."</p> <p>20 Q. And is this analysis that's described in 03:09:16 21 that table, does it breakdown each of the three 22 depression studies that were conducted by and funded 23 by GlaxoSmithKline?</p> <p>24 A. Yes.</p> <p>25 Q. And does that include Study 329, Study 377 03:09:33</p>	<p>1 A. No. 03:11:01</p> <p>2 Q. And what is emergent ideation?</p> <p>3 A. Suicidal ideation. Suicidal thoughts that 4 come out during the treatment for the first time.</p> <p>5 Q. And is that also true in worsening 03:11:14 6 ideation in terms of what comes out after the 7 treatment starts?</p> <p>8 A. Worsening would be presumably worsening 9 after the beginning of treatment.</p> <p>10 Q. Okay. Were there any deaths in pediatric 03:11:29 11 patients in Study 329?</p> <p>12 A. No.</p> <p>13 Q. Are you aware of any deaths that occurred 14 in any pediatric study and conducted by 15 GlaxoSmithKline? 03:11:43</p> <p>16 A. The FDA reported that there were no deaths 17 in any of the studies it had including those from 18 GSK.</p> <p>19 Q. So for either of these different analyses 20 that were carried out at a later date, which 03:12:03 21 included additional adverse events that were 22 analyzed from Study 329 and which you were involved, 23 did either of them show a statistically significant 24 increased risk of suicidal behavior with taking 25 Paxil versus placebo? 03:12:20</p>
<p>1 and Study 701? 03:09:35</p> <p>2 A. Yes.</p> <p>3 Q. And does it with respect to Study 329, 4 which you were involved in as a principle 5 investigator, does it show for the analysis of 03:09:50 6 suicide-related events which happened on-therapy 7 which were analyzed in this paper? Is there a 8 statistically significant increased risk of suicidal 9 related behavior for patients taking Paxil versus 10 those taking placebo? 03:10:07</p> <p>11 A. No.</p> <p>12 Q. Okay. Let's turn to table number six and 13 can you tell us -- that's on page 87, can you tell 14 us what the title of the table is?</p> <p>15 A. "Incidence of Emergent and Worsening 03:10:18 16 Ideation."</p> <p>17 Q. Again, does this table include an analyses 18 of the three pediatric depression studies that were 19 funded by GlaxoSmithKline, which include Study 329, 20 Study 377 and Study 701? 03:10:29</p> <p>21 A. Yes.</p> <p>22 Q. And with respect to Study 329 that you 23 worked on, does that show a statistically 24 significant increased risk of emergent or worsening 25 ideation? 03:10:58</p>	<p>1 A. No. 03:12:24</p> <p>2 Q. This study -- this analyses that was 3 published by Dr. Aptner and others, did that look at 4 the -- did it conduct these analysis in the context 5 of the on-drug period versus looking at on-drug plus 03:12:41 6 30 day period?</p> <p>7 MR. MURGATROYD: Are you talking about the 8 drafts or the final article?</p> <p>9 MR. DAVIS: Talking about the article that 10 was published. 03:13:05</p> <p>11 THE WITNESS: I'm going through this 12 quickly. We discussed yesterday while this was 13 published in January of this year I missed it 14 until yesterday and today. It does not appear 15 to include -- it appears to only include the 03:13:22 16 on-drug interval, but if you have other data 17 point me to the pages and I will look at that 18 and then give you a different answer -- give 19 you an appropriate answer.</p> <p>20 BY MR. DAVIS: 03:13:37</p> <p>21 Q. Okay. Turn back to Dr. Laughren's memo 22 that is dated January 5, 1994.</p> <p>23 MS. CONNELLY: Wait. Is this one of your 24 exhibits?</p> <p>25 MR. DAVIS: It's one of Plaintiffs 03:13:46</p>

<p style="text-align: right;">Page 210</p> <p>1 Exhibit. 03:13:48</p> <p>2 MS. CONNELLY: We don't have any of them.</p> <p>3 MR. MURGATROYD: Oh, I have some, which</p> <p>4 one are you looking for?</p> <p>5 MR. DAVIS: I'm not sure of the number. 03:14:11</p> <p>6 THE WITNESS: We discussed it today.</p> <p>7 MR. MURGATROYD: I don't have it, Todd.</p> <p>8 MS. CONNELLY: There's a bunch right here.</p> <p>9 MR. MURGATROYD: And we're looking for the</p> <p>10 Laughren memo? 07:59:58</p> <p>11 MS. CONNELLY: If it's from today it</p> <p>12 should be in the smaller pile.</p> <p>13 MR. MURGATROYD: It should be in here.</p> <p>14 Here it is. I got it.</p> <p>15 BY MR. DAVIS: 03:14:46</p> <p>16 Q. If you could look at page 15 that I opened</p> <p>17 that -- that document to and down at the bottom of</p> <p>18 that page, Dr. Ryan, is there a discussion by Dr.</p> <p>19 Laughren where the FDA has focused its attention in</p> <p>20 terms of looking on-drug versus on-drug plus a 30 03:15:52</p> <p>21 day period?</p> <p>22 A. Yes, it does.</p> <p>23 Q. And what does Dr. Laughren say about what</p> <p>24 the period the FDA will be looking at?</p> <p>25 A. This document says. "While we've been 03:16:11</p>	<p style="text-align: right;">Page 212</p> <p>1 a cogent argument why the on-therapy would be 03:17:24</p> <p>2 the first one to examine. It seems that the</p> <p>3 on-therapy plus 30 days, you know, may also be</p> <p>4 deserving of examination.</p> <p>5 (Defendants Deposition Exhibit No. 14 03:17:41</p> <p>6 was marked for identification.).</p> <p>7 BY MR. DAVIS:</p> <p>8 Q. Let me hand you what has been marked as</p> <p>9 Defendants Exhibit 14. Dr. Ryan, you mentioned that</p> <p>10 you had reviewed the analysis conducted by FDA on 03:18:03</p> <p>11 the pediatric studies which were performed by</p> <p>12 Dr. Hammond? Did I understand that correctly?</p> <p>13 A. That's correct.</p> <p>14 Q. And who is -- that's Dr. Terry Hammond?</p> <p>15 A. That's correct. 03:18:24</p> <p>16 Q. Who is Dr. Hammond at FDA?</p> <p>17 A. I don't know the answer to your question.</p> <p>18 Q. Is he a scientist at the FDA?</p> <p>19 A. Yes.</p> <p>20 Q. Let me turn your attention to page 45, 03:18:35</p> <p>21 which I've dog-eared to get you right to the</p> <p>22 section.</p> <p>23 A. I have that page.</p> <p>24 Q. Now, under "Reviewer's Conclusion", can</p> <p>25 you read the third bullet please? 03:18:46</p>
<p style="text-align: right;">Page 211</p> <p>1 provided data both for 'on-therapy' and for 03:16:14</p> <p>2 "on-therapy plus 30 days" events, I have focussed on</p> <p>3 the "on-therapy" data, since these are the least</p> <p>4 problematic from the standpoint of interpretation.</p> <p>5 While we do sometimes utilize them "on-therapy plus 03:16:31</p> <p>6 30 days" time frame for capturing events of</p> <p>7 interests, this analysis is problematic in this case</p> <p>8 for two reasons. First it may be confounded by</p> <p>9 discontinuation symptoms occurring following</p> <p>10 withdrawal of medication, and second, different 03:16:41</p> <p>11 sponsors used different rules in deciding what</p> <p>12 events to include and exclude the 30 days plus</p> <p>13 period in their analyses. For simplicity, I have</p> <p>14 provided the data for all ages combined, rather than</p> <p>15 breaking it out by age group." 03:17:05</p> <p>16 BY MR. DAVIS:</p> <p>17 Q. Do you agree that the more appropriate</p> <p>18 suicide related events would be looking at the</p> <p>19 on-drug therapy versus the on-drug therapy plus 30</p> <p>20 days? 03:17:20</p> <p>21 MR. MURGATROYD: Objection; calls for</p> <p>22 speculation; lack of foundation and lack of</p> <p>23 expertise.</p> <p>24 THE WITNESS: I agree that if one had to</p> <p>25 choose between the two that Dr. Laughren makes 03:17:24</p>	<p style="text-align: right;">Page 213</p> <p>1 A. "No individual trial showed a 03:18:46</p> <p>2 statistically significant signal for suicidality.</p> <p>3 However, many had a RR, risk ratio, of 2 or more and</p> <p>4 some of the overall estimates, across various trial</p> <p>5 groupings, were statistically significant." 03:18:59</p> <p>6 Q. Was Dr. Hammad's analysis of the</p> <p>7 suicidality events in the Paxil pediatric trial that</p> <p>8 were part of his analysis find a statistically</p> <p>9 significant increased risk for Study 329?</p> <p>10 MR. MURGATROYD: Objection; calls for 03:19:22</p> <p>11 speculation.</p> <p>12 THE WITNESS: The data is clear in here</p> <p>13 that it did not.</p> <p>14 BY MR. DAVIS:</p> <p>15 Q. And do you recall looking at the data on 03:19:33</p> <p>16 Study 329 when this data became available?</p> <p>17 A. I looked at the data on all the studies</p> <p>18 including that study when this data became</p> <p>19 available.</p> <p>20 Q. Now, you mentioned to Plaintiffs Counsel 03:19:44</p> <p>21 that one of the reasons you were no longer involved</p> <p>22 in the Aptner papers is because Dr. Hammand's</p> <p>23 analyses was more thorough? Do you recall that</p> <p>24 testimony?</p> <p>25 A. If I said more thorough that is not what I 03:20:03</p>

Page 214	Page 216
<p>1 intended to say. 03:20:07</p> <p>2 Q. What did you intend to say?</p> <p>3 A. Well, a better way of expressing it, it's</p> <p>4 more comprehensive, because adding data from all the</p> <p>5 compounds and putting it together that's of much 03:20:18</p> <p>6 more value to the field than looking at a single</p> <p>7 compound.</p> <p>8 Q. Okay. I think you answered my question.</p> <p>9 Thanks. Let me have you look at Exhibit 60, if you</p> <p>10 would? 03:20:46</p> <p>11 MS. CONNELLY: It should be in that pile,</p> <p>12 if you could please help me out.</p> <p>13 MR. MURGATROYD: Absolutely. I won't ask</p> <p>14 you to get paper clips.</p> <p>15 MR. DAVIS: It's right here. 03:20:46</p> <p>16 BY MR. DAVIS:</p> <p>17 Q. Dr. Ryan, Plaintiffs Counsel mentioned to</p> <p>18 you that you had received an inquiry from a reporter</p> <p>19 at Health Magazine, do you recall that?</p> <p>20 A. I think Dr. Keller received the inquiry 03:21:11</p> <p>21 and he asked me to help work on some of this.</p> <p>22 Q. And what was the time that inquiry was</p> <p>23 received by Dr. Keller?</p> <p>24 A. All I have is the notes from here, because</p> <p>25 otherwise I don't know. The first e-mail from here 03:21:28</p>	<p>1 THE WITNESS: I'm sorry. Can you repeat 03:22:37</p> <p>2 your question?</p> <p>3 MS. CONNELLY: How about ask him if he has</p> <p>4 any knowledge of the date.</p> <p>5 BY MR. DAVIS: 03:23:22</p> <p>6 Q. Let me show you what has been marked as</p> <p>7 Plaintiffs Exhibit 27. Do you see that's a copy of</p> <p>8 the FDA Talk Paper dated June 19, 2003?</p> <p>9 A. Yes.</p> <p>10 Q. Thank you. And does it discuss anything 03:23:35</p> <p>11 about submissions that GlaxoSmithKline has made to</p> <p>12 the FDA in the first paragraph?</p> <p>13 A. It says that "It's reviewing the reports</p> <p>14 of a possible increased risk." Let's see. It says,</p> <p>15 "New safety information is currently under review 03:23:58</p> <p>16 that was derived from trials of Paxil."</p> <p>17 And was there something that you would</p> <p>18 like me to comment on?</p> <p>19 Q. Yes. I was going to say, is that based</p> <p>20 upon the FDA Talk Paper dated June 2003? Does that 03:24:20</p> <p>21 refresh your recollection about the time that</p> <p>22 GlaxoSmithKline had submitted some analysis of</p> <p>23 adverse events, possible suicidal-related behavior</p> <p>24 in pediatrics?</p> <p>25 MR. MURGATROYD: Objection; misstates the 03:24:33</p>
<p>Page 215</p> <p>1 is dated March 16, 2004 from me to Dr. Keller. 03:21:29</p> <p>2 Q. Okay. And was that date after</p> <p>3 GlaxoSmithKline had submitted to FDA its analyses of</p> <p>4 pediatric suicidality events in the pediatric</p> <p>5 studies? 03:21:52</p> <p>6 A. If you can help me out on the date on that</p> <p>7 one I can tell you if that was before or after.</p> <p>8 MR. MURGATROYD: Let me object to lack of</p> <p>9 foundation.</p> <p>10 BY MR. DAVIS: 03:22:01</p> <p>11 Q. Are you aware GSK submitted to FDA</p> <p>12 analysis of suicide -- possible suicide related</p> <p>13 events in pediatric studies in May of 2003?</p> <p>14 MR. MURGATROYD: Objection; leading, and</p> <p>15 it misstates the evidence. Now, wait a minute. 03:22:13</p> <p>16 You can't do that, Todd. He submitted that in</p> <p>17 2002.</p> <p>18 MR. DAVIS: Excuse me?</p> <p>19 MR. MURGATROYD: The original was</p> <p>20 submitted in 2002. 03:22:24</p> <p>21 MR. DAVIS: The pediatric analyses were</p> <p>22 submitted in May of 2003.</p> <p>23 MR. MURGATROYD: I'll object for lack of</p> <p>24 foundation, and it's a leading question, and</p> <p>25 you're assuming facts not in evidence. 03:22:33</p>	<p>Page 217</p> <p>1 evidence. I don't think the Doctor ever said 03:24:33</p> <p>2 he knew at any time what the date was.</p> <p>3 THE WITNESS: I -- I -- even after looking</p> <p>4 at this I don't -- I don't know the date.</p> <p>5 BY MR. DAVIS: 03:24:48</p> <p>6 Q. Okay. How many months after the date,</p> <p>7 according to the e-mail that's been marked as</p> <p>8 Plaintiffs 60, was the Terry Hammond analyses</p> <p>9 published?</p> <p>10 A. The Terry Hammond analyses was published 03:25:07</p> <p>11 relatively recently. I haven't actually seen the</p> <p>12 published version just that one today, have I?</p> <p>13 Q. I'm sorry. I mean, what's been marked as</p> <p>14 Defendants Exhibit --</p> <p>15 A. I'm sorry. You meant published on the 03:25:18</p> <p>16 web?</p> <p>17 Q. Yes.</p> <p>18 A. Okay. Perfectly fair. It was published</p> <p>19 also in the journal, so this is ...</p> <p>20 Q. If you look at the very last page. 03:25:26</p> <p>21 A. That would be a help. So this is 4-16-04</p> <p>22 and this is --</p> <p>23 Q. This -- I'm sorry. I think it's</p> <p>24 August 16, '04, Doctor.</p> <p>25 A. You're completely right. August 16, '04, 03:25:44</p>

Page 218	Page 220
<p>1 and this is March 16, '04. 03:25:44</p> <p>2 Q. And were you aware that there was a</p> <p>3 Pediatric Advisory meeting on the use of SSRIs in</p> <p>4 treating pediatric patients in February of 2004?</p> <p>5 MR. MURGATROYD: Objection; leading. 03:26:11</p> <p>6 THE WITNESS: I am aware that there was a</p> <p>7 meeting in February 2004, yes.</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. And I'll hand you what's been marked as</p> <p>10 Plaintiffs Exhibit 38, which is a copy of the 03:26:13</p> <p>11 article dealing with Study 511 that was published by</p> <p>12 Dr. Braconnier. Doctor, is this a placebo</p> <p>13 controlled study?</p> <p>14 A. No.</p> <p>15 Q. What type of study is it? 03:26:37</p> <p>16 A. This was compared to another active</p> <p>17 compound.</p> <p>18 Q. Okay. And can one -- with respect to the</p> <p>19 suicide attempts that occurred with placebo,</p> <p>20 paroxetine and tricyclic antidepressants, can one 03:26:44</p> <p>21 calculate an incidence rate of possible suicide</p> <p>22 attempts in this study that it is not placebo</p> <p>23 controlled?</p> <p>24 MR. MURGATROYD: Objection; leading.</p> <p>25 THE WITNESS: Well, you have an incident 03:27:09</p>	<p>1 Q. And there's a page there that's dog-eared 03:29:01</p> <p>2 and highlighted, can you turn to that page?</p> <p>3 A. Yes.</p> <p>4 Q. And can you read that into the record,</p> <p>5 please, what you and your coauthors state in this 03:29:11</p> <p>6 article?</p> <p>7 A. "Selective serotonin Reuptake Inhibitors</p> <p>8 appear to be efficacious in pediatric major</p> <p>9 depressive disorder. Three randomized controlled</p> <p>10 trials report superiority of SSRI to placebo in 03:29:22</p> <p>11 Emslie et al.1997); Keller 2001; however, two failed</p> <p>12 to find SSRI superiority, one of fluoxetine, (et al</p> <p>13 1990) which had a high placebo response rate, and an</p> <p>14 industry-sponsored study of paroxetine (Milen et al</p> <p>15 1990)." 03:29:35</p> <p>16 Q. And is the reference to the Milan et. al,</p> <p>17 is that reference to a poster presentation that was</p> <p>18 made by Dr. Milan about the results of Study 377?</p> <p>19 A. Yes.</p> <p>20 Q. And was this article published in a 03:30:03</p> <p>21 peer-reviewed journal I think that was read by that</p> <p>22 physician?</p> <p>23 A. Yes.</p> <p>24 Q. And what year was this article published?</p> <p>25 A. 2002. 03:30:13</p>
<p>Page 219</p> <p>1 rate for each compound, but you do not have a 03:27:11</p> <p>2 ratio. You have a ratio between the two, but</p> <p>3 you have no way to judge what that would be</p> <p>4 over, you know, you have no way to attribute</p> <p>5 that to medication or happenstance because 03:27:22</p> <p>6 there's no control</p> <p>7 BY MR. DAVIS:</p> <p>8 Q. Let me ask you another question. Based</p> <p>9 upon the fact that this is not a placebo based</p> <p>10 trial, can one determine whether or not those events 03:27:39</p> <p>11 occurred as a result by study medication or by</p> <p>12 chance?</p> <p>13 A. No.</p> <p>14 (Defendants Deposition Exhibit No. 15</p> <p>15 was marked for identification.) 03:28:16</p> <p>16 Q. I'm going to hand you what's been marked</p> <p>17 as Exhibit 15. Doctor, can you read that article</p> <p>18 for us, please?</p> <p>19 A. Yes. This was an article that was</p> <p>20 published in 2002 in the Society -- the Journal of 03:28:37</p> <p>21 the Society of Biological Psychiatry entitled</p> <p>22 "Skating to where the Puck is Going to Be: A Plan</p> <p>23 for Clinical Trials and Translation Research in Mood</p> <p>24 Disorders". It was the result of a consensus</p> <p>25 conference I coauthored with along 30 other authors. 03:28:50</p>	<p>Page 221</p> <p>1 Q. Is that a year after the Keller et. al 03:30:14</p> <p>2 article was published?</p> <p>3 A. Yes.</p> <p>4 Q. And in this article, did you and the other</p> <p>5 authors disclose the efficacy results of Study 377 03:30:24</p> <p>6 in terms of whether or not Study 377 failed to find</p> <p>7 SS of SSRI superiority?</p> <p>8 A. Yes.</p> <p>9 Q. Now, was there ever any effort on your</p> <p>10 part to not disclose the results of Study 377 which 03:30:50</p> <p>11 you were aware of?</p> <p>12 A. No.</p> <p>13 Q. And by the that fact you published this</p> <p>14 information in a peer-reviewed journal, what did you</p> <p>15 try to inform physicians about the results of Study 03:31:05</p> <p>16 377?</p> <p>17 A. We were trying to give physicians the</p> <p>18 results of all studies that we knew the results of,</p> <p>19 because it's important to get all the data.</p> <p>20 Q. Now, did any one at GlaxoSmithKline try to 03:31:14</p> <p>21 prevent you from disclosing this information about</p> <p>22 Study 377?</p> <p>23 A. No.</p> <p>24 Q. Did any one at GlaxoSmithKline try to</p> <p>25 persuade you to present this data in some other way 03:31:22</p>

Page 222		Page 224	
1	in which it wouldn't describe the fact that Study 377 was not effective in showing superiority over placebo in that study?	03:31:28	
2			
3			
4	A. No.		
5	Q. Plaintiffs Counsel questioned you about a number of your slides that you brought today and shared with us in which you discussed the results of Study 329 and other clinical studies on pediatric patients. Did Plaintiffs Counsel ever tell you when Study 701 was completed?	03:31:58	
6			
7			
8			
9			
10		03:32:20	
11	A. Not to my memory.		
12	Q. Okay. I want to hand you what was marked as Plaintiffs Exhibit 36. Turn to page 3, which is a report synopsis, and I'll ask if you can read into the record what was the treatment date excluding the paper phase for Study 701 and what was the date of the final Study Report for 701?	03:32:43	
13			
14			
15			
16			
17			
18	A. The last -- the last dose of study medication excluding taper was admitted on 24, January 2001, and you asked me something -- a second thing to do and I've forgotten that.	03:33:05	
19			
20			
21			
22	Q. Yes, sir. What was the date of the final study report?		
23			
24	A. Final Clinical Report was dated 30, July 2001.	03:33:26	
25			
Page 223		Page 225	
1	Q. Okay. For the presentations that have been marked as exhibits here and for other presentations that you gave, could you have put any data about Study 701 in those slides presentations or discussed the results if the study had not been completed when you did those slides?	03:33:28	
2			
3			
4			
5		03:33:39	
6			
7	A. No.		
8	Q. Okay. And so how many slide sets could you have -- that the vast majority of the slide sets that you discussed with Plaintiffs Counsel predated January 2001 when Study 701 -- excuse me, thank you -- do you agree that the vast majority of the slide sets that you discussed with Plaintiffs Counsel predated July 2001 when the final study report was done for 701?	03:33:58	
9			
10			
11			
12			
13			
14			
15		03:34:20	
16	MR. MURGATROYD: Objection misstates the evidence. I think -- I mean, do you know that for a fact?		
17			
18			
19	MS. CONNELLY: I have the University's -- the nine slides presentations.	03:34:35	
20			
21	THE WITNESS: Okay. So the majority or the vast majority. Okay. 1, 2, 3, 4, 5, 6 --		
22			
23	MS. CONNELLY: What's the critical date again?		
24			
25	MR. MURGATROYD: July 2001.	03:34:39	
1	THE WITNESS: So I'm getting a December 2001 and a July 2001.	03:34:48	
2			
3	MR. MURGATROYD: There's another one right in front of you.		
4			
5	THE WITNESS: Is there another one?	03:34:48	
6	MS. CONNELLY: Oh, okay.		
7	THE WITNESS: May 2002. So I'm getting six of nine. The majority.		
8			
9	MS. CONNELLY: One is the same month.		
10	THE WITNESS: One is the same month and I don't know -- let's see if I can figure out when it was in it. I don't know. I think it was towards the end of the month so I think you've got either six of nine or seven of nine.	03:34:48	
11			
12			
13			
14			
15	BY MR. DAVIS:	03:35:20	
16	Q. And the final study report of 701 was finished -- I believe was finished on July 30, 2001.		
17			
18	A. Then you've got seven of nine.		
19	Q. Okay. Dr. Ryan, do you recall when you first learned of the study results of 701?	03:35:37	
20			
21	A. To the best of my knowledge that was 2004 on the FDA web site.		
22	Q. Do you remember any discussions that you had with GlaxoSmithKline employees before April of 2002 about the results of study 701 before GSK	03:36:26	
23			
24			
25			
1	submitted an indication -- for an indication to treat pediatric obsessive compulsive disorder?	03:36:33	
2			
3	A. I do not remember this.		
4	Q. There's also this Pediatric advisory committee Meeting --	03:36:44	
5			
6	A. I'm sorry. I'm sorry. My apologies. About the depression study or about the OCD study?		
7			
8	Q. The depression study.		
9	A. I do not remember discussing the depression study related to the OCD.	03:36:58	
10			
11	Q. Okay. And on what's been marked as Plaintiffs Exhibit 2.		
12			
13	A. Right.		
14	Q. Do you recall participating in person or by phone about a discussion about the results, the efficacy and safety results about the pediatric studies that had been conducted to date?	03:37:13	
15			
16			
17			
18	MR. MURGATROYD: Wait a minute. Correct me if I'm wrong, but I think the Doctor testified he wasn't part of that.	03:37:14	
19			
20			
21	BY MR. DAVIS:		
22	Q. I'm just asking, does he recall participating in person or by phone in the Pediatric Advisory Committee Meeting?		
23			
24			
25	A. I'm not remembering it. Let me look at	03:37:35	

Page 226	Page 228
<p>1 the slides and see if that refreshes my memory. I 03:37:48</p> <p>2 cannot say that for sure that I have seen this</p> <p>3 before. I remember it. There certainly was</p> <p>4 sometime through this interval -- I can't</p> <p>5 pinpoint -- some discussion with GSK employees about 03:38:52</p> <p>6 suicidality issues and what they're doing. I just</p> <p>7 can't remember more.</p> <p>8 (Ryan Deposition Exhibit No. 16</p> <p>9 was marked for identification).</p> <p>10 BY MR. DAVIS: 03:39:09</p> <p>11 Q. Let me hand you what's been marked as</p> <p>12 Defendants Exhibit 16 and ask you if you can</p> <p>13 identify that as an article that Dr. Karen Wagner</p> <p>14 published in the Psychopharmacology Bulletin?</p> <p>15 A. This appears to be as stated. A 03:39:28</p> <p>16 Psychopharmacology Bulletin article in the spring</p> <p>17 2003 by Karen Dineen Wagner so authored entitled</p> <p>18 "Paroxetine and Treatment of Mood and Anxiety</p> <p>19 Disorders in Children and adolescents."</p> <p>20 Q. And was Dr. Wagner a principal 03:39:41</p> <p>21 investigator in Study 329?</p> <p>22 A. Yes.</p> <p>23 Q. And was she a coauthor of the article</p> <p>24 known as the Keller et. al article that published</p> <p>25 the results of Study 329? 03:39:52</p>	<p>1 BY MR. DAVIS: 03:41:13</p> <p>2 Q. Doctor, do you recall reading this article</p> <p>3 when it came out?</p> <p>4 A. No.</p> <p>5 Q. Do you recall one way or the other if you 03:41:20</p> <p>6 read it?</p> <p>7 A. I don't remember one way or the other.</p> <p>8 Q. Okay.</p> <p>9 A. Certainly somewhere through here I think</p> <p>10 that Dr. Wagner there had a -- I think there may be 03:41:29</p> <p>11 other references to Dr. Wagner to this study that</p> <p>12 was not at the time published or presented at a</p> <p>13 meeting.</p> <p>14 Q. Let me ask you: Plaintiffs have made the</p> <p>15 claim in this litigation that Sally Laden or STI, 03:41:43</p> <p>16 who she was employed with, ghost-wrote the article</p> <p>17 that you coauthored which reported the results of</p> <p>18 Study 329? Is that claim true?</p> <p>19 A. I certainly -- I do not think it to</p> <p>20 be true. I certainly do not have evidence that 03:42:11</p> <p>21 would support it.</p> <p>22 Q. Did you have input into the contents of</p> <p>23 the Keller et. al article of which you were named</p> <p>24 coauthor?</p> <p>25 A. Yes. 03:42:22</p>
<p>Page 227</p> <p>1 A. Yes. 03:39:59</p> <p>2 Q. Okay. Turn to page 169 to that dog-eared,</p> <p>3 if you will. Actually, if you turn to page 170 --</p> <p>4 I'm sorry -- in the third paragraph that is down</p> <p>5 from the top. 03:40:18</p> <p>6 A. Yes.</p> <p>7 Q. Do you see where it says "In another</p> <p>8 multicenter, double-blind placebo-controlled trial</p> <p>9 of paroxetine treatment of children and adolescents</p> <p>10 with major depression, there was no statistically 03:40:29</p> <p>11 significant difference in the response rates between</p> <p>12 the paroxetine and placebo groups"?</p> <p>13 A. I do.</p> <p>14 Q. And do you understand that study refers to</p> <p>15 Study 701? 03:40:46</p> <p>16 A. Yes.</p> <p>17 Q. And do you see that Dr. Wagner is</p> <p>18 disclosing that trial did not reach statistical</p> <p>19 significance in terms of the efficacy parameters?</p> <p>20 A. Yes. 03:41:05</p> <p>21 MR. MURGATROYD: What's the date on that?</p> <p>22 THE WITNESS: It says Spring 2003.</p> <p>23 MR. MURGATROYD: And did you establish</p> <p>24 that the doctor read it?</p> <p>25</p>	<p>Page 229</p> <p>1 Q. Okay. Did Sally Laden or STI control the 03:42:24</p> <p>2 content of the Keller et al, article?</p> <p>3 A. No. In no sense did they control it.</p> <p>4 Q. Who controlled the content of the article?</p> <p>5 A. The authors. 03:42:37</p> <p>6 Q. The named authors?</p> <p>7 A. The named authors.</p> <p>8 Q. Okay. And do you know how many drafts</p> <p>9 were circulated -- commented on by the outside</p> <p>10 investigators? 03:42:48</p> <p>11 A. I do not. It would be multiple drafts,</p> <p>12 and I do not know the total number.</p> <p>13 (Defendants Deposition Exhibit 17,</p> <p>14 18, 19, 20, 21 was marked for identification.)</p> <p>15 Q. Doctor, I have given you Exhibit 18 and 03:44:22</p> <p>16 19 --</p> <p>17 MS. CONNELLY: Actually I only see 17 in</p> <p>18 his hand.</p> <p>19 THE WITNESS: I have 17 here. I'm sorry.</p> <p>20 I should actually be responding to your 03:45:46</p> <p>21 questions rather than ignoring you. 17 and 19</p> <p>22 are duplicated here.</p> <p>23 MR. DAVIS: I don't think so. I'll walk</p> <p>24 you through those.</p> <p>25 THE WITNESS: I have four distinct 03:45:50</p>

Page 230	Page 232
1 documents instead of five. 03:45:50	1 fair and square inputs on all aspects. 03:48:20
2 MR. DAVIS: That's different. That's 3 different. That's different. The thing on 4 this is 18. I'll fix that in a second.	2 Q. No let's look at the next marked exhibit, 3 which I think is 20.
5 THE WITNESS: Okay. There's no 18 exhibit 03:45:50 6 right now.	4 A. It's Exhibit 20. Has a handwritten date 5 of 4-14-99 saying it's related to -- it says -- I'm 03:48:29 6 sorry -- it looks like -- it's 4-24-99 is the date 7 on it.
7 BY MR. DAVIS:	8 Q. So is that another version of the draft?
8 Q. Okay. So we've got our Exhibits 17, 19, 9 20 and 21. Is that right, Doctor?	9 A. It's a later version and it's got further 10 edits on it. 03:48:46
10 A. Yes. That's correct. 03:46:43	11 Q. Okay. What does it say on the top 12 left-hand corner of that?
11 Q. And in reviewing those documents, do you 12 see on them -- particularly on Exhibit 17, what's 13 the date of Exhibit 17?	13 A. Says, "Edits made by Keller Incorporated. 14 All feedback received as of 4-14-99."
14 A. It appears to be December 18, 1998.	15 Q. Okay. And what's the last document that's 03:49:09 16 been marked?
15 Q. And do you recognize Dr. Martin Keller's 03:47:07 16 handwriting down at the bottom?	17 A. The last document is e-mail that's not 18 produced by my office from me to Barbara Ryan and 19 Brown, which was the way to get stuff to Marty then, 20 because he didn't have his own e-mail so it was sent 03:49:22 21 to this administrator with some more feedback on the 22 draft.
17 A. It's similar to Dr. Keller's handwriting. 18 I can't authentic it.	23 Q. Is that feedback from other authors of the 24 Keller et al. article?
19 Q. Okay. And do you see that article -- that 20 draft has multiple revisions on it? 03:47:28	25 A. Some of it's from Greg Clarke. More of 03:49:37
21 A. Yes.	
22 Q. And let's look at what's marked as Exhibit 23 19.	
24 A. Yes.	
25 Q. What's the date of that letter? 03:47:28	
Page 231	Page 233
1 A. The date of that letter is February 11, 03:47:29 2 1995.	1 it's from Greg Clarke. It may all be from Dr. Greg 03:49:43 2 Clarke. I cannot tell if it's multiple authors or 3 just Dr. Clarke.
3 Q. And does it have a memorandum that is 4 attached to it?	4 Q. Okay. Now, did -- based upon your review 5 of those drafts of the Keller et al. article, do you 03:49:58 6 believe that you had substantial input into the 7 content of that article?
5 A. Yes. 03:47:41	8 A. Yes.
6 Q. And what's the date of that memorandum?	9 Q. Has Paxil or Paxil -- my next series of 10 questions when I say Paxil I mean Paxil and Paxil 03:50:18
7 A. The memorandum is February 22, 1999.	11 CR. Okay, Doctor, just to speed this up? Is that 12 agreeable to you?
8 Q. Who is the memorandum addressed to and who 9 is it from?	13 A. Yes.
10 A. It's from Dr. Martin Keller. It's 03:47:46 11 addressed to the co-authors on Paxil, Imipramine 12 Adolescent Research, and it says, enclosed is draft 13 number three of the acute phase manuscript.	14 Q. All right. Now, has Paxil been approved 15 by FDA for use in pediatric patients? 03:50:41
14 Q. What does it say in the next sentence?	16 A. I do not believe so.
15 A. It says: Neal, Mike and Jim, meaning 03:47:59 16 myself, Mike Strober and Jim McCafferty, have edited 17 the first two drafts with me.	17 Q. And are you aware that pharmaceutical 18 companies do not promote or market their medications 19 for other uses?
18 Q. And does that refresh your recollection 19 that you edited the first two drafts of that 20 article? 03:48:13	20 A. Yes, I am. 03:50:48
21 A. Yes.	21 Q. And when you have a professional 22 association such as the APA, which is the American 23 Psychiatric Association or the Journal of the 24 American Academy of Child and Adolescent Psychiatry 25 or the new drug clinical evaluation unit that holds 03:51:01
22 Q. And is -- what's the purpose of Dr. Keller 23 in sending this out to the other coauthors of the 24 article?	
25 A. So that every coauthor on the article has 03:48:20	

Page 234		Page 236		
1	a conference or a symposium or the rules and	03:51:07	1 I may have answered incompletely, was that it's	03:53:28
2	guidelines about what a pharmaceutical company can		2 important for researchers to get the data out	
3	and cannot do in promoting its product?		3 there, and the part that I answered that wasn't	
4	MR. MURGATROYD: Objection; leading.		4 a complete answer is that this has an	
5	THE WITNESS: Each organization has its	03:51:20	5 unintended consequence of being a good mention	03:53:39
6	own rules, but they all have a great deal in		6 of being something that does likely increase	
7	common, which is that anything targeted or		7 the use of the compound even for unapproved	
8	developed by a company would have to be so		8 uses.	
9	identified and the rest -- any conflicts of		9 BY MR. DAVIS:	
10	interest or any potential conflict with authors	03:51:33	10 Q. When you presented findings on Study 329,	03:53:48
11	would have to be disclosed in the program, and		11 were you ever trying to increase Paxil sales in the	
12	at the beginning of the talks, and they all		12 pediatric population?	
13	work really hard to make sure that people		13 A. No.	
14	aren't biased.		14 Q. And when you presented findings on Study	
15	Q. Now, are there also rules about what	03:51:50	15 329 whether at scientific conferences or symposium	03:54:07
16	pharmaceutical company employees can do in terms of		16 or by way of a published article, were you trying to	
17	interactions with the attendees at the conference?		17 promote or market Paxil in the pediatric population?	
18	A. Yes.		18 A. Absolutely not.	
19	Q. And are there rules that -- concerning		19 Q. And when you were invited -- let's leave	
20	whether or not there are certain areas that are off	03:52:07	20 that go. 03:54:22	
21	limits for marketing or promotion?		21 At any time did any GlaxoKlineSmith	
22	A. Yes.		22 employee ever ask you or suggest to you that he or	
23	Q. And are those places that are off limits		23 she wanted you to present scientific data about	
24	where the scientific presentations or/and posters		24 Study 329 for purposes of increasing Paxil sales in	
25	are presented for review?	03:52:18	25 the pediatric population?	03:54:33
Page 235		Page 237		
1	MR. MURGATROYD: Let me just object on the	03:52:22	1 A. No. 03:54:35	
2	ground of lack of foundation. We haven't seen		2 Q. At any time, did any GlaxoSmithKline	
3	anything that establishes what you're saying.		3 employee ever ask you or suggest to you that you	
4	THE WITNESS: Yes.		4 should present data on the safety and efficacy	
5	BY MR. DAVIS: 03:52:35		5 findings of Study 329 for the purpose of promoting	03:54:58
6	Q. Do you have any evidence that		6 or marketing Paxil in the pediatric population?	
7	GlaxoSmithKline did not comply with those rules and		7 A. No.	
8	guidelines with respect to Paxil?		8 Q. When you were invited to speak at any	
9	A. No.		9 professional organization about the results of Study	
10	Q. And do you have any evidence that	03:52:44	10 329, at any time did anyone at GlaxoSmithKline ask	03:55:16
11	GlaxoSmithKline tried to market or promote Paxil for		11 you or suggest to you that you ought to do so for	
12	pediatric use at any scientific conference or		12 the purpose of marketing or promoting Paxil for use	
13	symposium?		13 in pediatric patients?	
14	A. No.		14 A. No.	
15	Q. And when you answered Plaintiffs Counsel	03:52:58	15 Q. And at any time that you presented data to	03:55:33
16	questions earlier in the deposition about what		16 professional organizations or physicians about the	
17	happens at scientific conferences or presentations		17 results of Study 329, did anyone at GlaxoSmithKline	
18	or through the publication of articles, did you mean		18 ask you or suggest to you that they wanted you to do	
19	to suggest in any way that GlaxoSmithKline intended		19 that for the purpose of increasing sales of Paxil to	
20	to or did, in fact, promote Paxil for use in	03:53:11	20 pediatric patients?	03:55:48
21	pediatric patients?		21 A. No.	
22	MR. MURGATROYD: Objection; leading,		22 Q. At any time, did anyone at GlaxoSmithKline	
23	misstates the evidence.		23 ask you to present data on pediatric data on	
24	THE WITNESS: That was not my intention.		24 pediatric studies involving Paxil that was not	
25	My intention in answering that question, which	03:53:28	25 scientifically accurate and reliable?	03:56:09

	Page 238		Page 240
1	A. No. 03:56:14	2	THE WITNESS: None of the 03:58:41
3	Q. Did you ever do so?	3	co-investigators. None of the authors of the
4	A. No.	4	article ever suggested such a thing.
5	Q. Did any one at GlaxoSmithKline ask or	5	BY MR. DAVIS:
6	suggest to you to do anything along the lines of 03:56:18	6	Q. Did any clinical investigator in Study 329 03:58:44
7	only presenting Paxil's positive data in Study 329?	7	or any author of the Keller et. al, article ever say
8	A. No.	8	to you that they had been asked by GlaxoSmithKline
9	Q. At any time did any one at	9	to present data on Study 329 either for the purpose
10	GlaxoSmithKline ever ask you or suggest to you that	10	of promoting or marketing Paxil in the pediatric 03:59:01
11	you should downplay or hide what may be viewed as 03:56:29	11	population or for increasing sales of Paxil in the
12	negative safety or efficacy data in pediatric	12	pediatric population?
13	studies including Study 329?	13	A. No.
14	A. Absolutely not.	14	MR. DAVIS: Thank you, Dr. Ryan. No
15	Q. When you gave talks or presentations about	15	further questions at this time.
16	the results of Study 329 even at scientific 03:56:44	16	MR. MURGATROYD: I think we're going to 04:07:16
17	conferences or meetings of physicians, who prepared	17	change the tape.
18	those presentations?	18	VIDEOGRAPHER: At this time we're going
19	A. Absolutely in all -- I prepared all my	19	off the record. The time is 4:00 p.m.)
20	slides. In two cases, both presented to your	20	(Recess taken)
21	industry, put their own backgrounds on them 03:56:59	21	VIDEOGRAPHER: We are now back on the 04:07:50
22	subsequently.	22	record. This is the beginning of Tape No. 6,
23	Q. Did GlaxoSmithKline control the contents	23	the deposition of Dr. Ryan. The time is
24	of any --	24	approximately 4:09 p.m. Please proceed.
25	A. No. They did not control the content in	25	BY MR. MURGATROYD:
	any way. They did not suggest any modifications of 03:57:11		Q. Doctor, you were shown a number of 04:08:07
	Page 239		Page 241
1	any slides. They did not change the content of any 03:57:11	1	exhibits by Mr. Davis that you stated accurately 04:08:11
2	slides.	2	reflected the information in your article, in the
3	Q. When you presented data on the safety and	3	329 article?
4	efficacy of Study 329 to physicians, whether it be	4	A. Yes.
5	in scientific conferences or meetings with 03:57:24	5	Q. Do you recall these Exhibits 6 and 7? 04:08:14
6	physicians or published literature, were you trying	6	A. Yes.
7	to present that data in a balanced view?	7	Q. Okay. Let's take a look at Exhibit --
8	A. All cases, yes.	8	which is the one with the table?
9	Q. At any time did any other clinical	9	THE WITNESS: 7.
10	investigator in Study 329 or coauthor of the Keller 03:57:44	10	MS. CONNELLY: 7. 04:08:24
11	article suggest or say to you that the authors	11	BY MR. MURGATROYD:
12	should present data about the results of Study 329	12	Q. 7. okay. And that lists the -- lists
13	for the purposes of promoting Paxil or increasing	13	eight efficacy variables, right?
14	sales of Paxil in pediatric patients?	14	A. Yes.
15	MR. MURGATROYD: Objection; compound, 03:58:13	15	Q. Four of which you testified were 04:08:37
16	asked and answered.	16	statistically significant, correct?
17	BY MR. DAVIS:	17	A. Yes.
18	Q. Well, I'll break it down. At any time,	18	Q. And how many of the four that were
19	Dr. Ryan, did any other of the clinical	19	statistically significant relate to the HAM-D?
20	investigators of Study 329 who were also coauthors 03:58:18	20	A. Two. 04:08:50
21	of the Keller et. al article ever suggest or ask you	21	Q. Okay. And have you ever been involved in
22	to present data on Study 329 for the purpose of	22	a conversation with Dr. Keller in which either you
23	increasing sales in pediatric patients?	23	or he trashed using the HAM-D in studies involving
24	MR. MURGATROYD: Objection; compound	24	adolescents?
25	question. 03:58:37	25	MR. DAVIS: Object to form. 04:09:16

<p style="text-align: right;">Page 242</p> <p>1 THE WITNESS: I think that Dr. Keller, Dr. 04:09:16 2 Emslie, myself, the entire field after this 3 study had said that the HAM-D was not as good 4 as the CDSRR. 5 MR. MURGATROYD: I think we're up to 62, 04:09:50 6 Todd? 7 MR. DAVIS: I think you're up to 65. 8 MR. MURGATROYD: Oh, good. 9 (Ryan Deposition Exhibit No. 65 was 10 marked for identification.) 02:47:32 11 BY MR. MURGATROYD: 12 Q. Okay. Let's see. let's take a look at 65. 13 A. Yes. 14 Q. And can you identify for the record, sir, 15 what that documents is? 04:10:18 16 A. It's a letter -- I'm sorry -- it's an 17 e-mail from me to Dr. Martin Keller, re: "in 18 response to the Jureidini -- entitled "Paxil 19 Response to the Jureidini Article", dated November 20 8, 2002 produced by my office. 04:10:37 21 Q. Okay. And in it, do you discuss the HAM-D 22 scales that were used in Study 329? 23 A. Yes. 24 Q. Sir, I'm not quite sure how to read them. 25 What -- do me a favor. It seems -- if you could, 04:10:58</p>	<p style="text-align: right;">Page 244</p> <p>1 positive -- or did Dr. Keller trash two of the 04:11:50 2 positive efficacy variables from Study 329? 3 A. Yes. This goes -- the issue is, was the 4 HAM-D a less sensitive measure of differences, and 5 so actually finding a statistically significant 04:12:07 6 difference on the HAM-D is harder to do and so it's 7 a little bit more impressive that we found it on 8 some of the measures from that. So the argument 9 where they're saying they've trashed it is that it's 10 not a sensitive change as the CDSRR. 04:12:22 11 Q. Okay. 12 A. And so that would go against your order -- 13 against the directional you're trying to argue? 14 Q. Well, I'm sorry. He said he trashed the 15 HAM-D. What's that again? 04:12:31 16 A. Right. That he -- and the rest of child 17 psychiatry is saying it's a less sensitive measure. 18 Q. Okay. 19 A. That we found a P value on this on a less 20 sensitive measure doesn't say we shouldn't report 04:12:44 21 it. It just says it's not a good choice for future 22 studies. 23 Q. Okay. And what did you decide -- or what 24 you stated in the reply to Dr. Jureidini was a 25 better instrument of measurement? 04:12:52</p>
<p style="text-align: right;">Page 243</p> <p>1 would you read the paragraph that starts with, "Heh 04:10:58 2 Neal." 3 A. "Heh Neal. Talked to Karen Wagner and 4 Boris Birhamer about this today and showed them 5 earlier draft. Boris suggested we say that our 04:11:01 6 measures that are positive." And then there is some 7 asterisks and all caps, "Careful we just trashed the 8 HAM-D and 2 of our positive measures are the H-D 9 less than 8 and the D depressed mood item. Have a 10 long tradition of use in other studies." I forgot 04:11:09 11 to put in the K-SADS depression item was also 12 positive. I don't have the reference in the AACAP 13 format (trivial change in text and format of 14 reference, just see recent article.) Can your office 15 do that since I don't get home until Saturday and 04:11:33 16 can't really do from road." 17 Q. Okay. And let's stop right there. And 18 was this you writing this or was this Dr. Keller 19 writing this? 20 A. No. This was Dr. Keller writing this. 04:11:39 21 Q. Okay. Writing that to you? 22 A. That's correct and to -- with cc's to Dr. 23 Birmaher and to Kelly MacNell who is someone at 24 Brown. 25 Q. And why did you trash the two of the 04:11:46</p>	<p style="text-align: right;">Page 245</p> <p>1 A. The field has moved strongly away from 04:13:01 2 using the Hamilton Depression Scale for depression 3 and is using the Child Depression Rating Scale 4 Revised. 5 Q. Okay. is that considered a better -- a 04:13:11 6 better scale? 7 A. Yes, because it's more sensitive to 8 changes that you see with medications. 9 Q. Okay. And did GSK perform a MDD study in 10 adolescents utilizing that scale, to your knowledge? 04:13:16 11 A. Yes. I think -- I think that every study 12 funded by industry since then, to my knowledge, 13 that's used a measure has used the CDSRR. 14 Q. Okay. And so you're aware that 701 used 15 that instrument, correct? 04:13:35 16 A. Yes. 17 Q. Okay. And in 701 did that instrument 18 reach statistical significance in favor of Paxil? 19 A. No. 20 Q. Okay. And the reason you didn't point 04:13:43 21 that out in this article is because you had not read 22 701 at the time you wrote this -- I mean, wrote this 23 reply to Dr. Jureidini? 24 A. That would be not the only reason, not the 25 most so substantive reasons, but one of the reasons. 04:13:58</p>

	Page 246		Page 248
<p>1 If I hadn't read it I can't point out that we used 04:13:58</p> <p>2 it in that one; but again, you're getting the</p> <p>3 direction wrong. That we used a less sensitive</p> <p>4 instrument to the change and found a significant P</p> <p>5 value, and that the whole field had moved away from 04:14:18</p> <p>6 that because the CDSRR looked better doesn't say</p> <p>7 that -- I mean, doesn't say anything bad about the</p> <p>8 Hamilton. It just said that you should move away</p> <p>9 from it. That a study using the CDSRR didn't find a</p> <p>10 difference doesn't say why the study didn't find a 04:14:28</p> <p>11 statistically significant difference.</p> <p>12 Q. I think you say in your reply to Dr.</p> <p>13 Jureidini. "The field has moved strongly away from</p> <p>14 using the Hamilton rating scale for depression in</p> <p>15 adolescent treatment studies", correct? 04:14:41</p> <p>16 A. The emphasis on the strongly was yours.</p> <p>17 It's not italicized; but yes, otherwise that was a</p> <p>18 correct quote.</p> <p>19 Q. Okay. And Dr. Jureidini criticized you</p> <p>20 for writing an article that confused the reader as 04:14:50</p> <p>21 to what response was, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. Okay. And one of the -- I think the --</p> <p>24 Exhibit 6 that Mr. Davis gave you defines response,</p> <p>25 do you see that? 04:15:09</p>	<p>1 through the parenthesis, please? 04:16:14</p> <p>2 A. "Of the depression-related variables,</p> <p>3 paroxetine separated statistically from placebo at</p> <p>4 endpoint among four of the parameters: Response.</p> <p>5 Q. Keep reading. 04:16:29</p> <p>6 A. I.e, primary outcome measure).</p> <p>7 Q. Okay. Let's there. That's not a true</p> <p>8 statement, is it?</p> <p>9 MR. DAVIS: Object to the form; it</p> <p>10 mischaracterizes the article. 04:16:31</p> <p>11 THE WITNESS: I think that's misstated.</p> <p>12 BY MR. MURGATROYD:</p> <p>13 Q. Okay. So you would agree what Dr.</p> <p>14 Jureidini criticized your article about in number</p> <p>15 one of his criticism in the letter to the editors, 04:17:31</p> <p>16 do you see that? "The definition of response is</p> <p>17 changed."</p> <p>18 A. That's a fair question. Let's go through</p> <p>19 it again. Perfectly fair question. You could read</p> <p>20 responses the first half of that in which case it 04:18:13</p> <p>21 makes it or the whole thing.</p> <p>22 Q. Sop it's confusing, correct?</p> <p>23 MR. DAVIS: Object to the form.</p> <p>24 THE WITNESS: Yes.</p> <p>25</p>		
<p>1 A. Exhibit 6, yes. 04:15:09</p> <p>2 Q. Okay. And what is response?</p> <p>3 A. The protocol described two primary</p> <p>4 measures, one either Hamilton-D less than 8 and/or</p> <p>5 50 percent reduction in baseline HAM-D or two change 04:15:18</p> <p>6 in the HAM-D total score.</p> <p>7 Q. Okay. And you agree that Paxil failed to</p> <p>8 reach statistical significance with regard to either</p> <p>9 of those efficacy variables?</p> <p>10 A. Yes. 04:15:31</p> <p>11 Q. Okay. Now, if you return to your article,</p> <p>12 sir.</p> <p>13 MS. CONNELLY: Do you have your article?</p> <p>14 THE WITNESS: I think the Keller article</p> <p>15 is right there. 04:15:39</p> <p>16 MR. MURGATROYD: That's the disappearing</p> <p>17 act article.</p> <p>18 BY MR. MURGATROYD:</p> <p>19 Q. And if you would, turn to page 765 at the</p> <p>20 bottom. 04:15:58</p> <p>21 A. Yes.</p> <p>22 Q. And do you see under that section it says</p> <p>23 "Efficacy Results"?</p> <p>24 A. Yes.</p> <p>25 Q. And can you read the first sentence 04:16:03</p>	<p>1 BY MR. MURGATROYD: 04:18:28</p> <p>2 Q. So Dr. Jureidini's criticism is well</p> <p>3 taken? Would you agree with that?</p> <p>4 MR. DAVIS: Object to form.</p> <p>5 THE WITNESS: It could be. It's 04:18:33</p> <p>6 confusing. I do not know that it was</p> <p>7 deliberately changed.</p> <p>8 BY MR. MURGATROYD:</p> <p>9 Q. Okay. Well --</p> <p>10 A. You know, I don't know whether you say 04:19:05</p> <p>11 it's changed. It is ambiguous in the way where it</p> <p>12 says where the response is just the HAM-D less than</p> <p>13 8 or response is both of those put together.</p> <p>14 Q. Well, what do we know response is? What</p> <p>15 was response? 04:19:09</p> <p>16 A. I think that was the point that I was</p> <p>17 agreeing with you on. It is confusing here.</p> <p>18 Q. Okay. Now, I asked you yesterday with</p> <p>19 regard to this article whether or not the secondary</p> <p>20 end-points had been defined what it called -- is it 04:19:31</p> <p>21 A-priority?</p> <p>22 A. Yes.</p> <p>23 Q. And I think you said that you did not</p> <p>24 believe that was true or you didn't recall?</p> <p>25 MR. DAVIS: Objection; mischaracterizes 04:19:41</p>		

Page 250	Page 252
<p>1 the testimony. It stands as it is. If you 04:19:44 2 want to ask another question and see if it's 3 already been answered.</p>	<p>1 BY MR. MURGATROYD: 04:22:16 2 Q. Well, let me ask you this. In terms of -- 3 what is the scientific definition of A priority?</p>
<p>4 BY MR. MURGATROYD: 5 Q. Okay. That's fine. Were the secondary 04:19:48 6 end-points, particularly the four that found in 7 favor of Paxil to a statistical significance 8 predefined?</p>	<p>4 A. Before the thing. 5 Q. And does that mean before the study is 04:22:26 6 started? 7 A. No. I don't think so. I mean, my best 8 understanding of the definition is no, that doesn't 9 mean that at all.</p>
<p>9 MR. DAVIS: Objection; asked and answered. 10 THE WITNESS: They were not to the best of 04:20:22 11 my knowledge predefined at the very beginning 12 of the study. They certainly were predefined 13 before we looked at the data.</p>	<p>10 Q. Have you heard it used that that's the 04:22:39 11 proper way to use that term? It's before the 12 study's started and not before the blind is broken? 13 MR. DAVIS: Object to form.</p>
<p>14 BY MR. MURGATROYD: 15 Q. Would that fall under the category of 04:20:33 16 A-priority? 17 A. Yes.</p>	<p>14 THE WITNESS: I have not heard it used 15 that way. 04:22:46 16 BY MR. MURGATROYD: 17 Q. Would you agree that it would be improper</p>
<p>18 MR; DAVIS: Asked and answered. 19 THE WITNESS: Yes.</p>	<p>18 to add an efficacy variable after the blind was 19 broken without so disclosing it in the paper? 20 A. It seems like there's two parts to that. 04:23:03 21 If you -- it would be improper? It would not 22 necessarily be improper.</p>
<p>20 BY MR. MURGATROYD: 04:20:39 21 Q. In fact, two of the efficacy were not 22 decided to be used until after the breaking of the 23 blind. A statement saying that they were predefined 24 would be incorrect? Is that correct?</p>	<p>20 Q. You would have to disclose it though, 21 correct? Isn't that called a post hoc analysis? 22 A. No. A post hoc -- you can make a few A 04:23:18 23 24 25</p>
<p>25 MR. DAVIS: Object to the form. 04:20:46</p>	
Page 251	Page 253
<p>1 THE WITNESS: No. The question is you 04:20:48 2 planned that analysis before you dredged the 3 data, and that's certainly one of perfectly 4 fair meanings of that priority.</p>	<p>1 priority hypothesis -- a post hoc analysis -- I do 04:23:20 2 not think you're using -- I don't think that's what 3 you're saying. Say it again.</p>
<p>5 If you go do a bunch of analysis and say 04:21:03 6 these come out that's not A Priority. If you 7 say I hypothesis in this area. Here's what we 8 need to look at. You don't know what the data 9 looks like. That's A priority.</p>	<p>4 Q. Okay. Let's go back to the original 5 question. 04:23:31 6 If you decide to use a secondary variable 7 after the blind is broken for the first time, what 8 is that called? 9 A. In general that would be called post hoc.</p>
<p>10 BY MR. MURGATROYD: 04:21:16 11 Q. Okay. So if you don't even analyze the 12 data until after the study is concluded and the 13 blind is broken, what is that called?</p>	<p>10 Q. Okay. And is it scientifically proper 04:23:48 11 then to -- if you're going to use that in a paper to 12 disclose that it was post hoc? 13 A. Yes.</p>
<p>14 MR. DAVIS: Objection to form. 15 THE WITNESS: Say it again. 04:22:01</p>	<p>14 Q. And would you agree that post hoc 15 variables are less scientific than those that are 04:24:03 16 predefined because you already know the answer when 17 you declare it's a variable?</p>
<p>16 MR. MURGATROYD: Can you read that one 17 back, please. 18 (Record read.)</p>	<p>18 A. No. 19 Q. Okay. When -- let me ask you this: Do 20 you still -- you know all the slides we talked 04:24:22 21 about today in which you state that -- the slide 22 states that Paxil is effective in the treatment of 23 adolescents with major depressive disorder? Do you 24 still give that lecture? 25 A. No. 04:24:26</p>
<p>19 THE WITNESS: Well, but I'm sorry. The 20 question still makes no sense, because you 04:22:01 21 can't analyse the data until the blind is 22 broken, and certainly there was no analysis of 23 any data related to treatment assignment until 24 the study was over.</p>	

Page 254	Page 256
<p>1 Q. Do you still use that slide? 04:24:35</p> <p>2 A. No.</p> <p>3 Q. Do you agree that if you would use that</p> <p>4 slide today knowing what you know now it would not</p> <p>5 by truthful? 04:24:50</p> <p>6 MR. DAVIS: Object to the form.</p> <p>7 THE WITNESS: I guess it depends on what</p> <p>8 you would say with the slide since the slide is</p> <p>9 just a prompt for discussion, but certainly I</p> <p>10 think that once you aggregate three studies up 04:24:52</p> <p>11 the evidence for Paxil being efficacious is</p> <p>12 relatively weak.</p> <p>13 BY MR. MURGATROYD:</p> <p>14 Q. Okay. And Mr. Davis had you read reviewer</p> <p>15 comments from the JAMA reviewers, do you remember 04:25:13</p> <p>16 that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Do you recall the reviewers from</p> <p>19 JAMA -- actually, before we discuss that, JAMA is</p> <p>20 the Journal of? 04:27:03</p> <p>21 A. The American Medical Association.</p> <p>22 Q. And you originally submitted your article</p> <p>23 on 329 to that publication?</p> <p>24 A. Yes.</p> <p>25 Q. And that was rejected, correct? 04:27:13</p>	<p>1 the people on active medication. 04:28:20</p> <p>2 Q. Well, actually this talks -- it doesn't</p> <p>3 talk about placebo. It says: Good clinical</p> <p>4 management.</p> <p>5 A. That's what they were talking about, the 04:28:29</p> <p>6 placebo group got good -- all of the groups</p> <p>7 including the placebo group got good clinical</p> <p>8 management.</p> <p>9 Q. And what's good clinical management mean?</p> <p>10 A. It's described in the paper. It's 04:28:33</p> <p>11 basically more medication management. They were</p> <p>12 talked to my a human being who cared about them.</p> <p>13 They were asked how they were doing. They were</p> <p>14 given general non-specific advise.</p> <p>15 Q. And do you agree, sir, that the majority 04:28:43</p> <p>16 of cases of mild depression spontaneously resolve?</p> <p>17 A. The majority of all cases of depression</p> <p>18 spontaneously resolve, but it's just that people</p> <p>19 suffer and have suicide and have bad functioning</p> <p>20 during the cases. 04:28:59</p> <p>21 Q. I'm sorry? I never heard that before.</p> <p>22 All cases of depression? Does severe depression</p> <p>23 spontaneously resolve?</p> <p>24 A. If you don't treat it for long enough</p> <p>25 other than the other chronic dysthymia, but you're 04:29:09</p>
<p>Page 255</p> <p>1 A. That's correct. 04:27:14</p> <p>2 Q. And there were reviewer comments, correct?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. Do you recall the comment, and I'll</p> <p>5 quote this. "This study could do more harm than 04:27:20</p> <p>6 good unless the authors devote much more attention</p> <p>7 in their discussion to the fact that the bulk of the</p> <p>8 effect in this study was the result of good clinical</p> <p>9 management and not the medication"? Do you recall</p> <p>10 reading that, sir? 04:27:39</p> <p>11 A. Yes.</p> <p>12 Q. Okay. What does that criticism mean to</p> <p>13 you?</p> <p>14 A. What it means is the people on placebo got</p> <p>15 quite a bit better and the people on medication in 04:27:46</p> <p>16 this study by some, but not all of the measures, got</p> <p>17 statistically significantly even better than that.</p> <p>18 Q. Do you agree that your study could do more</p> <p>19 damage than good?</p> <p>20 A. No. That same criticism would apply to 04:28:07</p> <p>21 every study that I'm aware of basically of</p> <p>22 antidepressant treatment certainly in children and</p> <p>23 most in adults that the response of people to</p> <p>24 placebo in terms of their clinical improvement is</p> <p>25 greater than -- is more than half of the response of 04:28:18</p>	<p>Page 257</p> <p>1 talking about major depression so over time they all 04:29:11</p> <p>2 have remissions and they all get better to the point</p> <p>3 where they all -- essentially all -- where they no</p> <p>4 longer meet major depression and then they get --</p> <p>5 most all of them -- 70 percent plus get worse again. 04:29:20</p> <p>6 Q. Okay. I'm talking about mild depression?</p> <p>7 A. But that's the case for all depression.</p> <p>8 That would include mild depression. They all over</p> <p>9 time get better.</p> <p>10 Q. Okay. Well, I'm just asking. I'm just 04:29:33</p> <p>11 talking about mild depression. Do you agree that</p> <p>12 cases of mild depression spontaneously resolve?</p> <p>13 A. I agree the cases of severe depression</p> <p>14 spontaneously resolve. Cases of moderate depression</p> <p>15 spontaneously resolve. Cases of psychotic 04:29:46</p> <p>16 depression spontaneously resolve, and cases of mild</p> <p>17 depression.</p> <p>18 Q. Okay. Now you were talking before about</p> <p>19 a -- like a relapse in depression and severely</p> <p>20 depressed, they get better and then get worse? 04:29:59</p> <p>21 A. We know that for most depressions, 70</p> <p>22 percent of -- in kids -- in children and adolescents</p> <p>23 have a recurrence over a five-year period.</p> <p>24 Q. And is that for kids who are mildly</p> <p>25 depressed? 04:30:11</p>

Page 258	Page 260
<p>1 A. There's no separate data that I'm aware of 04:30:16 2 that would pull that out.</p>	<p>1 (Ryan Deposition Exhibit No. 66 04:32:29 2 was marked for identification.)</p>
<p>3 Q. Now, you're aware that kids that have 4 killed themselves on Paxil, right.</p>	<p>3 Q. Let me show you what I'm marking as 4 Exhibit 66, sir, and we'll be talking about the</p>
<p>5 MR. DAVIS: Object to the form. 04:30:35</p>	<p>5 first paragraph of the third page that I'll be 04:32:39</p>
<p>6 THE WITNESS: I am aware that adolescents 7 have -- who are depressed have killed 8 themselves while being treated with Paxil.</p>	<p>6 asking you to read into the record. 7 THE WITNESS: Could you read back your 8 last question though, please.</p>
<p>9 BY MR. MURGATROYD:</p>	<p>9 MR. MURGATROYD: You can have the court 10 reporter do that. 04:32:41</p>
<p>10 Q. Okay. Are you aware of kids who were 04:30:46 11 given Paxil for other reasons than depression who 12 have killed themselves?</p>	<p>11 (Record read.)</p>
<p>13 A. I'm not aware of it.</p>	<p>12 BY MR. MURGATROYD:</p>
<p>14 Q. Okay. Is that information that would be 15 important to you? 04:31:01</p>	<p>13 Q. Well, so it's clear, no active 14 participation in taking care of the patients in your 15 study? 04:33:37</p>
<p>16 A. Individual cases of -- the question of 17 suicidal risks with all these compounds is overly 18 important. Individual cases don't let you assess 19 anything more about that risk, unfortunately.</p>	<p>16 A. I'm sorry. You said was -- was my opinion 17 in that matter because I did not have active 18 participation?</p>
<p>20 That's why it's been so hard to study. So as a 04:31:13 21 human being, of course, it would be interesting to 22 me. As a scientist, unfortunately, those are not 23 informative as to whether Paxil was causable that.</p>	<p>19 Q. Yes.</p>
<p>24 Q. Well, do you agree that -- well, in your 25 study you looked at whether or not -- or you were 04:31:16</p>	<p>20 A. It was not because of that. I answered 02:47:32 21 no.</p>
<p>Page 259</p>	<p>22 Q. Okay. Let's take a look at this document.</p>
<p>1 asked to determine whether or not a serious adverse 04:31:16 2 event that you observed in your patient was related 3 to the drug either possible, probably, definitely or 4 not at all, correct?</p>	<p>23 A. Yes. That is it. 24 MS. CONNELLY: Document 66 appears to be a 25 SmithKline Beecham document subject to the 04:34:05</p>
<p>5 A. Right. 04:31:39</p>	<p>Page 261</p>
<p>6 Q. And is that something that there's 7 criteria that's set up that you try to use to 8 determine that?</p>	<p>1 protective order which the Plaintiff -- which 04:34:05 2 Dr. Ryan has not seen before.</p>
<p>9 A. No, unfortunately not.</p>	<p>3 BY MR. MURGATROYD:</p>
<p>10 Q. Well, actually, you've listed those in 04:31:50 11 e-mails, haven't you? Different criteria for 12 determining that? Didn't it list it in the protocol 13 on how to do that?</p>	<p>4 Q. Okay. And it is a document entitled 5 "Confidential Final Report Investigator Audit 04:34:18 6 Report", correct?</p>
<p>14 A. Not to my knowledge.</p>	<p>7 A. Yes.</p>
<p>15 Q. Well, is that because you didn't have any 04:32:05 16 relationship with the patients in your study?</p>	<p>8 Q. Okay. And it has a date, right? "Final 9 Report Date" on the front page?</p>
<p>17 A. No.</p>	<p>10 A. 9-11-98. 04:34:28</p>
<p>18 Q. Well, are you aware of what an audit is to 19 install a study by a drug company?</p>	<p>11 Q. So that was after the study was concluded, 12 correct?</p>
<p>20 A. Yes. 04:32:16</p>	<p>13 A. Yes.</p>
<p>21 Q. Are you aware that an audit was done on 22 your site?</p>	<p>14 Q. Okay. And if you'll turn to the third 15 page. 04:34:35</p>
<p>23 A. Yes.</p>	<p>16 A. Uh-huh.</p>
<p>24 Q. Have you seen the results of that audit?</p>	<p>17 Q. Top paragraph.</p>
<p>25 A. No. 04:32:28</p>	<p>18 A. Yes.</p>
	<p>19 Q. Will you read that into the record, 20 please. 04:34:39</p>
	<p>21 A. "The study was started at the site with 22 only Dr. Ryan as the PI. One year into the study 23 Dr. Birmaher was added as the co-PI."</p>
	<p>24 Q. Not too fast.</p>
	<p>25 A. "This action should have taken place 04:34:44</p>

Page 262	Page 264
<p>1 sooner, as it appears that Dr. Ryan had no active 04:34:50</p> <p>2 role in the study. All assessments and study</p> <p>3 activities were performed by the study coordinators,</p> <p>4 Dr. Birmaher, and the other MD subinvestigators."</p>	<p>1 ask for more time I'm going I want to put my 04:36:59</p> <p>2 client in the best position to oppose such</p> <p>3 Motion. I told you all from the beginning I</p> <p>4 don't want to come back.</p>
<p>5 Q. Okay. And is that a true statement? 04:35:05</p> <p>6 A. Yes. Essentially true. I did a little</p> <p>7 bit of covering for Dr. Birmaher, but only on</p> <p>8 vacations.</p>	<p>5 Now, he's only had three hours. If at 04:37:09</p> <p>6 the end of the day what I'm left with if he</p> <p>7 goes to the judge and says, Judge, I tried to</p> <p>8 help this along. I only got three hours.</p>
<p>9 Q. Okay. Now, in Table three of your study</p> <p>10 Mr. Davis asked you about that table, I believe? 04:35:24</p> <p>11 A. Yes.</p> <p>12 MS. CONNELLY: Two minutes.</p>	<p>9 Would have had more cushion if we would have</p> <p>10 started on time. 04:37:16</p> <p>11 MR. MURGATROYD: Now, wait a minute. The</p> <p>12 cushion hurt me not Mr. Davis. It started</p>
<p>13 BY MR. MURGATROYD:</p> <p>14 Q. Table three. Do you see that?</p> <p>15 A. Yes. 04:35:41</p>	<p>13 late. That took away from my time.</p> <p>14 MS. CONNELLY: That's true.</p> <p>15 MR. MURGATROYD: That did not take away 04:37:28</p> <p>16 from Mr. Davis' time.</p>
<p>17 Q. And from reading that table, Doctor, can</p> <p>18 you tell how many adolescents tried to kill</p> <p>19 themselves on Paxil?</p> <p>20 A. No.</p>	<p>17 MS. CONNELLY: You're right.</p> <p>18 MR. MURGATROYD: We had and an agreement.</p> <p>19 We either hold to the -- did he agree to the</p> <p>20 agreement? 04:37:31</p>
<p>21 Q. Okay. Mr. Davis asked you questions about 04:35:50</p> <p>22 different letters that you responded to the editor</p> <p>23 regarding your article?</p> <p>24 A. Yes.</p>	<p>21 MS. CONNELLY: Yes.</p> <p>22 MR. MURGATROYD: Good. Then I insist that</p> <p>23 we hold to the agreement or I got another 50</p> <p>24 questions and I'll take it to another day.</p>
<p>25 Q. Is it true that Sally Laden, the outside</p> <p>medical writer, helped you with the bulk of the 04:36:14</p>	<p>25 MR. DAVIS: Come on. Come on. 04:37:37</p>
Page 263	Page 265
<p>1 responses -- all of those with the exception of the 04:36:14</p> <p>2 one you drafted in respect to Dr. Jureidini?</p> <p>3 MR. DAVIS: Object to the form.</p>	<p>1 MS. CONNELLY: You're not going to insist 04:37:37</p> <p>2 on anything.</p> <p>3 MR. DAVIS: Come on, Skip.</p>
<p>4 THE WITNESS: Ms. Laden helped with the</p> <p>5 first one. I don't remember whether she helped 04:36:28</p> <p>6 with the second one.</p> <p>7 BY MR. MURGATROYD:</p>	<p>4 MS. CONNELLY: This attitude of I'm going</p> <p>5 to do what I want doesn't lie. You don't have 04:37:41</p> <p>6 that power. Don't dilute yourself. You don't</p> <p>7 have the power to --</p>
<p>8 Q. And is she a Doctor?</p> <p>9 A. No.</p> <p>10 MR. MURGATROYD: Thank you. I have no 04:36:31</p> <p>11 further questions.</p>	<p>8 MR. MURGATROYD: I can subpoena this</p> <p>9 witness any time I want.</p> <p>10 MR. DAVIS: Come on. 04:37:59</p>
<p>12 MR. DAVIS: Can I just have two follow-up</p> <p>13 questions, ma'am?</p> <p>14 MR. MURGATROYD: Nope. A deal's a deal,</p> <p>15 dude. 04:36:46</p>	<p>11 MS. CONNELLY: Well, I hope it's an</p> <p>12 effective subpoena next time. He's doing his</p> <p>13 civic duty. He's here. He's produced thousand</p> <p>14 of pages of documents. We could have had the</p> <p>15 two questions done by now. 04:38:01</p>
<p>16 MR. DAVIS: Is that all right?</p> <p>17 MS. CONNELLY: Well, he did only have</p> <p>18 three hours and you had --</p> <p>19 MR. MURGATROYD: That was the deal. We</p> <p>20 either go by the deal or not. 04:36:58</p>	<p>16 MR. MURGATROYD: Are you going to hold to</p> <p>17 the deal or not? That's all I want to know?</p> <p>18 MR. DAVIS: For two questions that will</p> <p>19 take two minutes?</p>
<p>21 MR. DAVIS: Come on.</p> <p>22 MR. MURGATROYD: Listen, Todd, I've had</p> <p>23 you do this to me too many times.</p> <p>24 MS. CONNELLY: Listen. My analysis is if</p> <p>25 one of you two area going to go to a judge and 04:36:58</p>	<p>20 MR. MURGATROYD: No, because then I'll 04:38:11</p> <p>21 have questions after that and then we go on --</p> <p>22 and you did it to me in Philadelphia and it</p> <p>23 pissed me off and I'm not going to allow it</p> <p>24 again.</p> <p>25 MR. DAVIS: Skip -- 04:38:18</p>

Page 266		Page 268			
1	MR. MURGATROYD: You were on. You said an	04:38:20	1	the agreement. I've listened. I've gauged	04:39:46
2	hour and a half. You went on for three hours,		2	this deposition on exact time frames.	
3	Todd.		3	MR. DAVIS: You did not. You did not.	
4	MR. DAVIS: Skip, you gave --		4	MR. MURGATROYD: What are you talking	
5	MR. MURGATROYD: I refuse to be put in	04:38:20	5	about? Have I abided by the time frames that	04:39:50
6	that position again, because I agreed to knock		6	you set forth in your letter?	
7	out over 30 questions for Mr. McCafferty		7	MR. DAVIS: Come on. We're talking ten	
8	because of your representations.		8	minutes.	
9	MR. DAVIS: You're absolutely distorting		9	MS. CONNELLY: I'm thinking.	
10	what happened. Okay?	04:38:33	10	MR. DAVIS: We're talking ten minutes.	04:40:09
11	MR. MURGATROYD: You came to that		11	MS. CONNELLY: Let me talk to my client	
12	deposition. You said you had a day and then it		12	for a second.	
13	went into three days. You had three days. I		13	VIDEOGRAPHER: We are now going off the	
14	had a few hours. Come on. Be realistic.		14	record at 4:41 p.m.	
15	Todd, I've --	04:38:37	15	(Recess taken)	04:40:18
16	MR. DAVIS: You've asked the question that		16	VIDEOGRAPHER: We're now back on the	
17	--		17	record. The time is 4:43 p.m. Please proceed.	
18	MR. MURGATROYD: I'm not going to argue		18	MS. CONNELLY: The parties had prior to	
19	about it. The record will make it very clear		19	the deposition reached an agreement as to the	
20	that --	04:38:44	20	time that would be allowed for Dr. Ryan's	04:41:48
21	MR. DAVIS: Then you --		21	depositions.	
22	MR. MURGATROYD: I move to strike all of		22	The deposition has proceeded	
23	your testimony after we stipulated on the		23	substantially in accordance with the agreement;	
24	record how long you would go.		24	that being said, the defense agreed to a	
25	MR. DAVIS: We didn't stipulate on the	04:38:52	25	significantly shorter period of time than the	04:42:05
Page 267		Page 269			
1	record. We outlined what was going to happen	04:38:52	1	Plaintiff was allowed. I think the difference	04:42:09
2	in order to get the deposition complet4ed.		2	was 11 hours versus 3 hours.	
3	MR. MURGATROYD: Pam, Doctor, we had an		3	In light of that allocation of time I'm	
4	agreement. I insist that it be held by. If		4	going to allow the witness to be questioned by	
5	Todd wants to come back to ask his two	04:39:05	5	the Defense five minutes and the Plaintiff five	04:42:18
6	questions you can do that. I will not		6	minutes. I understand the Plaintiff says he	
7	participate in that.		7	objects to this. If he chooses to waive the	
8	MS. CONNELLY: We could also, Todd, you		8	opportunity to his five minutes then he chooses	
9	could call me and we could talk about doing an		9	to waive that opportunity and the parties to	
10	affidavit or we could do it here right now in	04:39:16	10	this case can fight it out with the Judge once	04:42:29
11	front of everybody. I mean, we don't want to		11	we have left. So you have five minutes, Mr.	
12	do that.		12	Davis and you have five minutes Mr. Murgatroyd.	
13	MR. DAVIS: What are you afraid of? What		13	MR. MURGATROYD: So the record's is	
14	are you afraid of?		14	absolutely clear I object to this. This is a	
15	MR. MURGATROYD: Because you'll start	04:39:24	15	breach of the agreement. I move to strike any	04:42:39
16	asking questions and then I'm going to want to		16	testimony that is taken after this moment, and	
17	ask questions and then all of a sudden I'm		17	to agree that any testimony is allowed after	
18	going to be told by Counsel here, I'm sorry,		18	this I will go back to the Court and re-open up	
19	Mr. Murgatroyd. Your time is long up.		19	this deposition for at least one to two more	
20	MR. DAVIS: If I take five minutes, will	04:39:33	20	days.	04:42:58
21	you allow Mr. Murgatroyd ten minutes?		21	MR. DAVIS: You know, in fairness Skip,	
22	MR. MURGATROYD: And then it --		22	you covered an issue with the witness that was	
23	MS. CONNELLY: I'm not going to -- I could		23	not covered during your multiple hours, and to	
24	let you do five and five. That's it.		24	let me leave and not allowing me to ask	
25	MR. MURGATROYD: I don't agree to break	04:39:46	25	questions about that when you did not go into	04:43:01

Page 270	Page 272
1 it -- 04:43:01	1 beginning to end including that data that's in the 04:44:48
2 MS. CONNELLY: Gentlemen, let's go. Let's 3 go.	2 table two as well as a description twice of what is 3 a primary end-points, do you believe that article is
4 MR. MURGATROYD: My objection is on there 5 and we will take it up with our Judge in Orange 04:43:16 6 County, California.	4 confusing or misleading or wrong in any way about 5 what are the primary end-points? 04:45:11 6 A. No, I do not.
7 MS. CONNELLY: The threaten of a punitive 8 two-day additional deposition of the witness is 9 improper. Let's go.	7 MR. MURGATROYD: Objection; leading. 8 THE WITNESS: No, I do not. 9 MR. DAVIS: Thank you, Doctor.
10 MR. MURGATROYD: That's your opinion. 04:43:24 11 That's how many more days I think I need with 12 this witness and I have a lot of cases I can 13 do --	10 MR. MURGATROYD: Sorry you broke your 04:45:20 11 agreement. We're going off the record. 12 Doctor, I'll probably see you again. Thank you 13 very much.
14 MS. CONNELLY: It's funny that you bring 15 that up in anger at the end of this deposition 04:43:26 16 when you're unhappy about this additional five 17 minutes.	14 MS. CONNELLY: No. On the record. Mr. 15 Murgatroyd has waived his opportunity for his 04:45:24 16 additional five minute rebuttal testimony of 17 Dr. Ryan.
18 MR. MURGATROYD: Mo. It's because Mr. 19 Davis also went into areas that I did not 20 discuss at all with the doctor so we'll discuss 04:43:37 21 that with the Judge. That's why we have 22 judges.	18 Dr. Ryan, you have the right to review 19 your testimony for any errors, typographical or 20 substantive and send it back or you can waive 04:45:33 21 your signature. 22 MR. MURGATROYD: Actually, that's not
23 EXAMINATION 24 BY MR. DAVIS:	23 California law. There's a standard stipulation 24 we use in all these cases.
25 Q. Dr. Ryan, with respect to the article that 04:43:39	25 MS. CONNELLY: We're not stipulating to 04:45:48
Page 271	Page 273
1 you coauthored that discussed the results of Study 04:43:41 2 329, do you believe that article clearly outlined 3 what were the secondary -- excuse me -- do you 4 believe the article that was published on the 5 results of Study 329, which you authored clearly 04:43:59 6 outlined what was a primary end-point for the study?	1 anything that's standard. We are under the 04:45:48 2 Federal Rules of Civil Procedure and -- 3 MR. DAVIS: He's kind of in a box as I 4 would be in trying to preserve the original. 5 It's a minute stipulation. 04:45:52 6 MS. CONNELLY: He still gets the 7 opportunity to review his deposition, correct?
7 A. Yes.	8 MR. DAVIS: Of course.
8 Q. Now, how many places in the article is the 9 primary end-point discussed?	9 MR. MURGATROYD: By stipulation.
10 A. At least quite clearly. 04:44:16	10 Stipulation between Counsel. Between Party of 04:46:13
11 Q. When someone reads the article from 12 beginning to end, including the tables, do you 13 believe that article is in any way misleading or 14 confusing to anybody about the primary end-points of 15 Study 329? 04:44:29	11 Counsel is that under the code in California 12 we're going to relieve the court reporter of 13 her duties, which requires her to maintain the 14 original. So we are relieving her of those 15 duties. She is going to send me the original. 04:46:26 16 She will send -- I think it can either go to 17 Todd first or to you first for the Doctor's 18 review and signature. Which would you care?
16 MR. MURGATROYD: Objection; asked and 17 answered.	19 MS. CONNELLY: Well, me. Todd --
18 THE WITNESS: It was certainly not our 19 intention to mislead people. I think it is 20 particularly clear, because it is in the 04:44:39 21 abstract as well as later. So I think that 22 it -- I think that finding those things and -- 23 I think we did a good job about being clear 24 about that.	20 MR. MURGATROYD: Well, Todd's going to end 04:46:41 21 up with your copy unless you're going to keep a 22 copy. Are you going to order a copy? 23 MS. CONNELLY: I may to put with this 24 file. Like I said, I was on the tail one this. 25 So send me Dr. Ryan's transcript and I'll 04:46:48
25 Q. So if a physician reads that article from 04:44:46	

Page 274

1 forward it to him. 04:46:58

2 MR. MURGATROYD: Right. And it's going to
3 be agreed that within 30 days of him making any
4 changes you're going to notify me?

5 MS. CONNELLY: Yes. 04:47:03

6 MR. DAVIS: Okay. You can do that either
7 directly or through Mr. Davis.

8 MS. CONNELLY: So do I -- normally you
9 send the errata sheet back to the court
10 reporter? 04:47:14

11 MR. MURGATROYD: No, that goes -- that's
12 why we're doing -- in California we do it a
13 little bit different.

14 MS. CONNELLY: Okay. If there's any other
15 instructions you can just send me a letter. 04:47:20

16 MR. MURGATROYD: And also as part of the
17 stipulation is for any reason the original is
18 lost a certified copy can be used at time of
19 trial.

20 MR. DAVIS: So stipulated. 04:47:24

21 MS. CONNELLY: So stipulated.

22 VIDEOGRAPHER: That now concludes this
23 Video Deposition. The time is 4:48 p.m.
24 (Ending time: 4:28 p.m.)
25

Page 275

1 REPORTER'S CERTIFICATION

2 I, Michele Kohar, Court Reporter certify;
3 that the foregoing proceedings were taken by
4 me at the time and place therein set forth;at
5 which time the witness was put under oath by me;

6 That the testimony of the witness, the questions
7 propounded, and all the objections
8 and statements made at the time of the examination were
9 recorded stenographically by
10 me and were thereafter transcribed;

11 That the foregoing is a true and correct
12 transcript of my shorthand notes so taken.

13 I further certify that I am not a relative
14 or employee of any of the attorneys of the parties, nor
15 financially interested in the
16 action.

17 I declare under penalty of perjury under the laws
18 of Pennsylvania that the foregoing is
19 true and accurate.

20 Dated this 7th day of September, 2006.
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A

- AACAP** 243:12
abided 268:5
able 142:20
absence 143:17,18
absolute 117:1
absolutely 65:10
82:12 84:14 85:8
163:18 214:13
236:18 238:13,18
266:9 269:14
abstract 153:11,15
153:18,24 154:7
157:11 185:7
271:21
abuse 136:16
abusive 49:3
Academy 112:18
161:10,11,14,15
161:21 162:2,6
182:10 183:15
195:24 196:14
202:4 233:24
acceptable 110:18
145:14
Accidents 137:4
accomplishing
190:9
account 204:7
accounted 107:14
accounts 76:22
accumulate 119:11
accuracy 61:14,24
accurate 72:1
122:23 155:10
177:25 186:17
237:25 275:19
accurately 93:4
154:5,24 241:1
achieve 42:9,23
171:17
achieved 171:8
ACNP 33:25 34:1
62:17
act 247:17
acted 71:4
action 261:25
275:16
actions 9:6
- active** 87:8 146:1
164:2 171:8
218:16 256:1
260:13,17 262:1
activities 262:3
acute 107:15,17
204:3 231:13
add 54:16 170:5
252:18
added 46:9 50:11
50:17,18,20
261:23
adding 214:4
addition 55:22
97:15 122:13
151:4,12 168:5,9
additional 57:17
82:8 83:1,4 85:19
97:7,20 206:9
208:21 270:8,16
272:16
address 29:15
69:20 107:18
165:13
addressed 107:23
185:8 231:8,11
addresses 116:3
197:12
addressing 197:11
Adelaide 184:5,7,8
184:8
adequately 107:23
135:1,6
adjudge 188:12
adjudicated
101:16
administration
116:15
administrator
232:21
Admission 152:7
admitted 222:19
adolescence
134:22
adolescent 6:9
13:12 20:21 25:9
32:1,7 34:16
35:19 62:23 87:1
87:1 103:4,5
109:1 112:5,8,19
- 132:20,22 133:9
134:24 135:22
140:22,23 146:23
159:25 161:12,21
162:3,7 165:12
169:7 170:10
172:3 177:17
179:22 180:1
182:11 183:16
185:18 186:24
188:1 192:2
195:5,11,17,25
196:14 197:17
199:11 202:4
206:11 231:12
233:24 246:15
adolescents 12:15
14:9 21:12 22:18
23:20 27:12
40:23 61:3 64:18
89:12,13 105:11
113:20 116:16
117:23 119:16,21
119:25 120:2,18
121:7,10 122:3
125:8,10 127:16
127:20 128:4,18
129:6 132:4
133:15,17 134:2
134:7,10,12
135:1,8,12
136:22,25 137:11
138:17 139:9
140:9,18 142:23
145:18 147:13
152:14 155:17
163:16 165:23
170:16,18 175:18
180:16 181:5,13
203:6 205:19
206:1 226:19
227:9 241:24
245:10 253:23
257:22 258:6
262:17
adult 127:10,14
133:9 134:15
135:19 166:1
172:17 192:3
adulthood 135:2,9
- adults** 27:12
116:11 120:7,12
133:16,17 134:21
135:13,17 144:1
192:11,21 255:23
adverse 79:2,3,5
80:3 83:10
105:10 150:6
199:2,5,5,16,21
200:21,23 201:6
202:12 203:5,9
203:15 204:8,13
204:15 205:5,20
205:21 206:5,9
208:21 216:23
259:1
advise 256:14
advisory 91:7
93:17,21 101:4
218:3 225:4,24
affect 20:8 21:8
25:5 31:21
affidavit 267:10
afraid 267:13,14
afternoon 110:6
after-suicide 94:8
age 119:13 129:11
130:21 133:23
211:15
agents 163:16
ages 211:14
aggregate 165:3
166:3 167:9
254:10
aggregated 70:2
Agnell 118:5
ago 40:4 71:8
102:24 106:11
agree 21:16,22
29:16 45:6,9,17
45:19 56:6,22
61:6,11,22 62:3
63:23 66:6 71:24
89:16 92:18,25
95:3 96:8 113:4
130:17 142:19
147:20 184:12
211:17,24 223:12
247:7 248:13
249:3 252:17
- 253:14 254:3
255:18 256:15
257:11,13 258:24
264:19 267:25
269:17
agreeable 233:12
agreed 51:22 114:3
146:10 147:25
266:6 268:24
274:3
agreeing 249:17
agreement 55:16
114:18 264:18,20
264:23 267:4
268:1,19,23
269:15 272:11
ahead 44:14 49:12
187:23 197:7
201:11
akathisia 27:25
28:2,9,13 29:5,6
29:10,17
al 8:15,16,19,21,25
9:1 116:12 118:3
118:4 185:24
186:13 194:11
202:8 203:7
204:11 220:12,14
220:16 221:1
226:24 228:23
229:2 232:24
233:5 239:21
240:6
Alan 74:14 82:3
205:24
Alberta 202:7
allegations 99:1
alleged 101:13
Alliance 5:1 36:5
allocation 269:3
allow 158:4 265:23
267:21 269:4
allowed 162:8
268:20 269:1,17
allowing 18:5
269:24
al.1997 220:11
ambiguous 144:9
184:18 249:11
American 4:21 5:6

- 32:18 33:11,25
62:16 64:6
112:18 161:10,11
161:14,15,21
162:2,6 182:10
183:15 193:16,24
194:5 195:24
196:13 202:4
233:22,24 254:21
Amor 9:11
amount 96:14
102:2 147:10
analyse 251:21
analysed 55:21
156:22
analyses 53:17
56:4 65:11,12
76:4 77:1,2 78:5
86:2,8 93:5 118:5
127:25 128:5
138:12 174:12
175:23 188:19
207:17 208:19
209:2 211:13
213:23 215:3,21
217:8,10
analysis 52:8,20
53:15 54:6,8
55:20 58:6 75:24
175:4,16 176:2
176:19,20 177:1
205:5,9 206:4,8
206:20 207:5
209:4 211:7
212:10 213:6,8
215:12 216:22
251:2,5,22
252:24 253:1
263:24
analyze 51:4 55:2
58:3 164:6
251:11
analyzed 46:18
47:6 50:11,17,18
50:20 55:18 56:6
58:18 59:16 78:8
120:25 148:18
155:20 156:4
160:23 175:10
207:7 208:22
- and/or** 70:17,20
75:19 159:1
204:5 247:4
anecdotal 192:19
Angeles 3:5
anger 270:15
animal 117:17
Ann 2:4 8:25
annual 107:8
annually 104:11
answer 7:9 42:5,13
44:8,9 45:25 46:1
55:13,15 56:1
60:4 61:20 71:23
72:2 89:8 94:21
95:13 106:11
108:7 110:16
114:9 126:19
128:8 139:3
141:13 143:1
180:12 187:4
209:18,19 212:17
236:4 253:16
answered 39:22
44:7 48:25 50:6
55:11 103:19
105:6 138:23,24
139:4 180:11
214:8 235:15
236:1,3 239:16
250:3,9,18
260:20 271:17
answering 53:3
82:16 172:2
235:25
answers 88:16
anticipated 146:1
antidepressant
11:4 91:19
163:15 187:18,18
197:14 255:22
antidepressants
23:20 89:23
117:3,14 118:7
118:14 119:2
138:7 144:1
146:6,17 195:5
195:16 218:20
anxiety 35:3
226:18
- anxiety/somatiz...**
51:8 52:19 175:9
176:16
anybody 36:15
44:15 46:5 147:7
271:14
APA 18:6 233:22
apologies 23:21
25:1 115:16
225:6
apologize 189:24
198:23
appear 74:3 82:19
94:4 122:17
209:14 220:8
appearance 9:11
appeared 70:23
79:2
Appearing 92:15
appears 19:12
68:10 74:13
88:14 104:15
108:3 174:21,25
186:5 193:18
196:1,19 206:13
209:15 226:15
230:14 260:24
262:1
appended 82:7
appendices 51:17
Appendix 92:11
apply 255:20
approach 139:25
146:11
approached
145:11
approaching 146:8
appropriate 177:9
209:19 211:17
appropriately
172:17
approval 15:22
167:24 188:11
approved 167:25
233:14
approving 188:6,6
189:15,16 190:1
190:1
approximately 8:4
17:17 49:18
- 68:21 87:5 96:24
109:23 127:19
128:21 129:11
152:6 158:10,14
179:3 240:23
approximation
165:18
April 4:9 11:20
202:5 224:24
Apter 83:13 98:17
205:24
Aptner 209:3
213:22
area 15:12,12
197:13 251:7
263:25
areas 234:20
270:19
argue 48:13
184:25 244:13
266:18
argument 37:18
122:8 212:1
244:8
argumentative
49:2
arguments 204:4
arm 82:9
arms 16:19 201:1
article 6:14,15,16
6:25 67:20 82:11
112:3,9,11,15,21
112:22 113:5
115:11 118:3,4
122:25 125:22
150:14,22 153:2
153:15,18 154:9
154:25 155:11
156:4,12,14
157:16,21 158:18
160:13,20,23
162:1,8,14,21
170:23 177:11
178:6,18 179:16
179:19 184:14
185:7,25 186:13
194:11 199:16,22
201:3 202:13
204:12 209:8,9
218:11 219:17,19
- 220:6,20,24
221:2,4 226:13
226:16,23,24
228:2,16,23
229:2,4 230:19
231:20,24,25
232:24 233:5,7
236:16 239:11,21
240:3,6 241:2,3
242:19 243:14
245:21 246:20
247:11,13,14,17
248:10,14 249:19
254:22 262:22
270:25 271:2,4,8
271:11,13,25
272:3
articles 28:22 71:1
141:16 161:2,9
161:13,15,20,23
202:11 235:18
Article/conclusion
6:17
asked 30:25 37:2
39:22 47:18 50:6
52:23,24 54:15
55:18 56:14
58:18 67:5 69:8
71:8 87:24 88:3
91:12 98:5 105:6
107:18 110:17
137:21 139:1
151:17,20 161:20
180:10 214:21
222:20 239:16
240:7 249:18
250:9,18 256:13
259:1 262:10,20
266:16 271:16
asking 36:17 41:2
50:10 55:10
82:10 89:9 98:23
105:5 130:3,8
190:5 225:22
257:10 260:6
267:16
asks 49:10 83:21
aspects 188:4
232:1
assert 97:19

asserted 69:25
 194:9
assertion 17:4 71:3
 88:6
assertions 45:14
 97:24 98:6,14
assess 147:12
 163:9 164:21
 174:5 176:22
 191:8,16 192:7
 258:18
assessed 164:12
 171:12,20 173:18
 188:19
assessing 165:11
 165:22 166:22
 173:22 175:8,16
 189:19
assessment 41:13
 113:2 118:9
 120:1,9,11
 151:14 185:3
 192:24,25 201:4
assessments 174:4
 262:2
assignment 251:23
assist 206:4
assisting 202:21
associated 27:23
 28:20 96:21
 131:15 167:19
 203:5
association 5:6
 29:10 64:6 91:18
 161:11 193:16,24
 194:6 233:22,23
 254:21
assume 18:14
 19:13 64:10
 74:19 85:1
 109:15 110:16
 119:20 137:18
 183:1
assumes 89:25
 172:4
assuming 215:25
asterisks 243:7
astutely 187:20
ATKINSON-BA...
 1:23

ATLANTA 3:9
attached 18:6
 231:4
attachment 18:2,3
 19:14
attempt 83:6 109:4
 160:18
attempted 105:18
 136:17
attempting 59:6
attempts 92:7
 132:1,15,18
 133:21,22 134:8
 134:9,10 218:19
 218:22
attend 15:14
attendees 234:17
attention 22:17
 51:17 121:23
 170:22 177:10
 192:15 193:21
 194:8 210:19
 212:20 255:6
attitude 265:4
attorneys 275:14
attributable
 203:10
attribute 219:4
audience 40:11,11
 40:17 41:17 42:1
 42:12,15,22
 43:18 44:1 64:20
audiences 11:10,12
 42:8
audit 6:6 259:18
 259:21,24 261:5
August 54:15
 217:24,25
Australia 184:5,8
 184:10
authentic 12:9
 15:24 18:13,15
 24:4 31:11 32:20
 59:8 63:21,25
 74:3,5,7,18,20,20
 75:9 81:14 88:19
 88:24 104:14
 108:2 183:6
 196:4 230:18
authenticating

193:19
author 125:23
 240:6
authored 150:23
 226:17 271:5
authors 76:2
 112:10,12 150:17
 194:9,10 196:13
 199:15 201:4
 202:19 204:11
 219:25 221:5
 229:5,6,7 232:23
 233:2 234:10
 239:11 240:2
 255:6
Autonomous
 171:21 173:20
available 12:21,23
 22:23,24 25:14
 32:10 71:4 82:18
 117:4 138:16
 140:22 204:22
 205:1 213:16,19
Avenue 8:6
average 44:22,23
 113:16 115:25
 136:12 151:24
 152:1,6,8,20
averaged 44:24
averages 136:4,7
avoidant 134:20
aware 25:24 38:24
 39:1 46:4 47:4
 57:8 60:7 65:12
 65:14 67:6,15
 89:21 97:23 98:5
 98:7,9,14 115:8
 125:17,20 127:12
 127:12,16,22,25
 136:20 137:8,11
 137:20,23,25
 138:2 173:17,24
 208:13 215:11
 218:2,6 221:11
 233:17 245:14
 255:21 258:1,3,6
 258:10,13 259:18
 259:21
A-priority 249:21
 250:16

a.m 2:16 8:2,4
 17:14,17 49:15
 49:18 66:23 67:2
 68:18,21 109:23
A008101 1:25

B

back 14:20 17:16
 26:17 34:6 39:13
 43:21 46:25 47:2
 48:15,21,23
 49:17 54:18,19
 66:25 68:20
 84:23 85:21,23
 107:5 109:25
 127:15 138:21
 158:13 161:8
 188:14 191:11
 193:23 195:24
 202:17 209:21
 240:20 251:17
 253:4 260:7
 264:4 267:5
 268:16 269:18
 272:20 274:9
Background 91:20
backgrounds
 238:20
bad 125:4 165:16
 168:13 189:4
 246:7 256:19
balance 16:23
balanced 14:12
 239:7
Barbara 232:18
Barcelona 4:8 12:1
based 48:5 94:13
 126:16 134:23
 144:14,20,23
 161:18 199:9
 216:19 219:8,9
 233:4
baseline 154:3,4
 154:21,22 159:1
 171:7 247:5
basic 33:15
basically 10:22
 33:19 62:18 73:3
 255:21 256:11
basis 119:8

bates 99:19 100:10
BAUM 3:4
Beecham 1:6,18
 2:7 8:16,20 9:1
 145:11,13 260:25
began 149:11
beginning 67:1
 110:1 145:23
 158:15 201:17
 208:9 234:12
 240:21 250:11
 264:3 271:12
 272:1
begins 142:7
behalf 1:2,3,13,14
 2:4,13 104:17
behavior 138:19
 140:4 171:3,10
 207:9 208:24
 216:23
behavioral 139:8
 139:17 140:7
 141:8,10 203:18
behaviors 92:4
 171:7 199:6,11
 206:1,10
Belfast 4:17 23:17
belief 73:10,12
believe 10:10
 16:15 36:13 39:8
 58:15 64:25
 73:13 74:6,10
 113:7 129:17
 138:23 141:20
 144:15,21,24
 145:20 146:3,12
 146:21 160:13
 161:19 162:5,15
 163:8 166:22
 167:2,6 175:15
 175:22 177:19,21
 177:24 178:5,6
 178:15 179:23
 180:21,24 181:24
 183:21 186:16
 188:24 189:19
 190:5,7,9 195:14
 196:15 198:20
 224:17 233:6,16
 249:24 262:10

271:2,4,13 272:3
believed 162:9
 201:5
belonged 53:22
benefit 121:17
 142:15,17 143:19
 144:22 184:20
 189:20 205:16
benefits 106:3,3,5
 144:7,16
benign 116:13
 120:4
best 14:11 25:14
 25:22 28:24
 35:21 38:25 42:2
 62:4 66:12,14
 71:22 75:10 78:6
 79:17 81:15 84:8
 97:4,15 98:18
 99:2 103:10
 106:4 135:10
 168:8 198:10
 204:21 224:21
 250:10 252:7
 264:2
better 84:13
 132:19 157:24
 160:7 162:19,24
 164:22 165:15
 166:8,8,12,12
 168:16,25 169:2
 173:3,13 185:18
 186:23 188:4
 191:2 192:10,15
 192:18 214:3
 244:25 245:5,6
 246:6 255:15,17
 257:2,9,20
Beverly 1:2 8:15
biased 234:14
Biddle 9:12
big 87:24 120:10
 120:15 121:19
bigger 138:3
Biological 219:21
bipolar 41:8
 130:22 131:3
Birhamer 243:4
Birmaher 35:13
 112:12 113:14

147:9 148:24
 149:12 198:12
 243:23 261:23
 262:4,7
birth 137:13
bit 23:19 96:16
 98:19,21 192:20
 244:7 255:15
 262:7 274:13
bits 124:25 125:2
 128:9
Blain 1:11,12,14
 8:19
blank 19:5
blended 127:18
blind 42:25 54:16
 150:11 250:23
 251:13,21 252:12
 252:18 253:7
blinded 83:12 98:1
 98:16,19 150:3
 206:6
blood 137:14
blues 152:13
board 104:9
 105:24,25 107:20
 161:17,19
body 188:6 189:15
 190:1
bonus 97:16,17
borderline 134:21
Boris 35:13 112:12
 148:24 243:4,5
bottom 90:23
 91:13,25 124:21
 131:8 151:3
 210:17 230:16
 247:20
Boulevard 3:5
box 27:6,9,10
 31:16 273:3
boyfriend 204:4
Braconnier 218:12
breach 269:15
break 49:2,6,10,11
 49:13,21 67:5,11
 239:18 267:25
breakdown 206:21
breaking 42:25
 211:15 250:22

breaks 103:3
Brent 112:13
briefly 64:5
bring 190:11
 270:14
brings 26:16
broadly 35:9
broke 80:7 272:10
broken 54:16
 251:13,22 252:12
 252:19 253:7
Brooks 1:13,15,15
brought 10:6
 222:6
Brown 232:19
 243:24
bulk 255:7 262:25
bullet 13:21,22,23
 21:15 31:19,23
 31:25 128:10
 129:3,4 131:13
 131:23 133:6,8
 133:18,20,25
 134:18 212:25
Bulletin 7:1 226:14
 226:16
bullets 131:11
 133:6
bunch 210:8 251:5
Bushnell 174:23
B.M 184:2,6

C

C 3:1
calculate 218:21
calculations 103:6
California 1:1 3:5
 8:13 270:6
 272:23 273:11
 274:12
call 82:21 267:9
called 74:15
 108:21 121:6
 128:25 131:9
 249:20 251:13
 252:24 253:8,9
calls 115:1,21
 116:23 121:12
 125:16 137:16
 139:11 140:5

141:1 143:1
 144:9 145:4
 148:16 156:5
 161:5 181:7,15
 211:21 213:10
Canada 202:7
cancer 137:12
caps 243:7
captures 188:4
capturing 164:8
 211:6
carbon 73:5
cardiotoxic 146:5
cardiovascular
 117:9
care 49:8 106:19
 129:24 260:14
 273:18
cared 256:12
careful 115:14
 243:7
Carpenter 5:8,13
 72:24 74:14 75:6
 82:2 94:7,11
Carpenter's 94:19
 94:23
carried 52:18,22
 53:4 55:20
 208:20
carrying 96:15
case 1:5,17 8:14,18
 87:20 90:2 94:14
 140:13 152:13
 196:20 205:13,16
 211:7 248:20
 257:7 269:10
cases 52:16 79:24
 83:2,4,11 238:19
 239:8 256:16,17
 256:20,22 257:12
 257:13,14,15,16
 258:16,18 270:12
 272:24
categorized 166:10
category 250:15
Cathedral 3:13
causable 258:23
cause 29:17,22
 136:21,24 137:8
 138:3

caused 27:20
 143:19
cc 1:6 5:18
ccd 73:8 82:3
 101:1
ccs 82:6
cc's 243:22
CDSRR 242:4
 244:10 245:13
 246:6,9
cell 85:21
cells 85:19 152:5
Center 100:20,22
 100:25
central 175:23
certain 59:8 65:1
 99:3 102:1 137:5
 198:20 234:20
certainly 19:16
 23:4,25 53:19
 65:15 72:2,10
 78:24 89:19 91:8
 94:23 101:23,23
 102:2,3 114:18
 144:11 146:24
 148:21 169:9
 193:18 196:2
 226:3 228:9,19
 228:20 250:12
 251:3,22 254:9
 255:22 271:18
CERTIFICATI...
 275:1
certified 2:17
 274:18
certify 275:2,13
CGI 157:5 165:20
 166:6,10 168:22
 169:2
chain 15:22
chairman 107:22
challenging 82:14
 98:20,21
chance 34:22
 46:24 69:5 91:11
 219:12
change 24:1 44:21
 57:25 66:22
 79:22 83:9 84:20
 85:20 109:5

- 154:3,22 201:9
201:11,14 239:1
240:16 243:13
244:10 246:4
247:5
changed 106:4,5
248:17 249:7,11
changes 129:13
164:1 245:8
274:4
changing 109:6
characterization
55:16 57:18 58:1
58:8 77:10
characterize 95:12
152:8,12
characterizing
58:12
charge 190:1
charged 188:6
189:15
chart 70:11 100:9
103:17
check 119:23
Checklist 171:22
173:20
cherry 194:17
child 11:11 15:20
35:3,8 109:1
112:5,7,19
117:11 122:14
129:1 132:20,22
133:9 134:24
135:22 140:21,23
141:6 145:19
146:23 149:5
161:12,21 162:3
162:7 182:10
183:15 195:25
196:14 197:13
202:4 233:24
244:16 245:3
Childhood 6:9
children 11:3,5
23:20 108:23
113:20 116:16
117:18,23 119:16
119:20 120:2,17
121:7,10 122:2,5
125:7,9 127:21
- 128:18,21 131:18
131:21 132:4,15
132:16,18 133:15
133:17 134:3,8
134:11,13,16,22
134:25 135:14
138:16 139:10
140:9,10,18
142:23 146:20,24
151:18 163:16
170:16 173:24
176:9,12,15
181:5,12 184:3
187:8 188:16,23
192:10,20 206:1
226:19 227:9
255:22 257:22
Children's 188:2
Child's 151:13
choice 244:21
choices 163:23
choose 106:19
188:15,22 211:25
chooses 269:7,8
Chris 15:20
chronic 113:1,9
137:13 256:25
chronological
74:11
chronologically
203:22
circulated 182:23
229:9
circulating 183:11
citation 119:18,22
119:24
cited 25:14
civic 265:13
Civil 273:2
claim 228:15,18
clarifying 40:6
clarity 161:23
Clarke 232:25
233:1,2,3
class 121:20
classification
79:25
classified 70:16,16
79:7 80:7
classify 80:3,9
- classifying** 79:15
79:16
clear 18:9 43:15
50:17,22 57:11
72:7 76:3 96:5
113:25 129:21
185:1,5 188:17
213:12 260:13
266:19 269:14
271:20,23
clearest 92:8
clearly 26:2 37:7
71:5 105:3 116:5
160:14 163:24
173:2 176:2
185:6 196:25
197:15,22 271:2
271:5,10
client 264:2 268:11
clinical 5:3 6:24
44:19 51:15 63:6
63:10 64:21 79:4
121:1 122:6
131:9 133:4,8
138:5 144:5,6,16
144:18,22 145:10
147:23 149:12,14
157:7 163:5
164:20 165:20
166:2 172:12
173:17 174:2
184:6 185:10
189:20 192:20
197:13 198:3
204:14,22 205:1
205:3 219:23
222:8,24 233:25
239:9,19 240:5
255:8,24 256:3,7
256:9
clinician 166:7
clinicians 33:20
170:9,13,15
188:11
clinician's 166:3,4
clips 214:14
close 75:21 99:12
169:11,15
coauthor 153:16
226:23 228:24
- 231:25 239:10
coauthored 154:25
155:11 156:13,15
157:11,22 158:19
160:14,21 170:23
177:12 178:3,7
179:19 184:14
185:21 193:6
205:24 219:25
228:17 271:1
coauthors 15:16
181:22 182:13,23
186:2,10 196:22
220:5 231:23
239:20
code 273:11
coded 92:4
codes 126:5
cogent 212:1
cognitive 51:10
138:19 139:7,17
140:4,7,11 141:7
141:10 175:9
176:7,14
Cold 4:24 35:3,9
collaborated 172:7
colleague 149:1
colleagues 45:19
61:11,16,22 62:3
117:6 120:25
129:16 132:14
181:25
College 4:21 32:18
33:11,25 62:16
Columbia 132:14
133:13 165:25
column 170:24
combination
156:24 174:5
combined 87:23
89:16,18 100:1
137:9,12 211:14
come 14:7 19:12
85:18 99:12
117:18 120:22
168:10,16 184:9
205:19 208:4
251:6 263:21
264:4,25,25
265:3,10 266:14
- 267:5 268:7
comes 85:21 208:6
coming 118:11
192:13
commenced
120:19,20
commencing 2:16
comment 59:4
87:24 182:3
194:15 216:18
255:4
commented
160:24 229:9
comments 59:12
99:16 107:9
184:12 193:15,22
193:23 194:13,18
194:25 195:23
197:20,24 254:15
255:2
commercial
119:11
committee 91:8
93:17,21 94:10
101:4 107:7
225:5,24
common 131:6
234:7
Comolli 204:6
companies 233:18
company 12:3 85:7
146:11 234:2,8
234:16 259:19
compare 117:15
compared 134:13
139:19,23 146:2
159:9 199:12
218:16
comparing 117:13
comparison 158:5
comparisons
171:15 177:4,5
complete 42:16
65:11 79:18
82:17 194:19
236:4
completed 36:22
36:23 37:2
107:15 113:19
121:9 122:14,16

125:25 126:6 136:17 148:7 222:10 223:6 completely 58:8 71:24 72:1 165:16 217:25 completing 107:17 completed 267:2 complex 185:14 186:19 complicated 43:11 comply 235:7 component 28:6 composite 175:7 compound 44:21 145:6 147:1 148:2,20 158:1 162:12 166:23 167:25 170:17,18 186:3 188:25 189:6 214:7 218:17 219:1 236:7 239:15,24 compounds 57:21 57:22 119:13 121:20,22 144:2 146:1,15 164:2 214:5 258:17 comprehensive 214:4 compulsive 225:2 concern 65:17 73:16 76:19 91:17 117:24 118:21 concerned 52:21 70:23 73:4 76:11 76:24,25 77:3 concerning 119:5 121:9,9 152:17 174:12 175:4 178:2 184:13 202:13 204:13 234:19 concerns 118:3,5 concluded 9:24 70:4 251:12 261:11 concludes 274:22 conclusion 43:7	177:11,14 178:2 178:3 179:18 180:9 181:3 212:24 conclusions 181:22 conclusively 179:20 180:18 conditions 138:1,4 conduct 146:13 199:6 200:10 203:17 204:6 209:4 conducted 105:22 143:7 178:22 179:6 206:22 208:14 212:10 225:17 conducting 103:1 145:12 146:9 192:8 conference 82:21 148:16 219:25 234:1,17 235:12 conferences 235:17 236:15 238:16 239:5 Confidential 261:5 confirm 18:7 133:2 conflict 93:23 94:1 101:17 234:10 conflicted 93:19,20 102:7 conflicts 234:9 confounded 211:8 confuse 160:19 confused 130:5 246:20 confusing 248:22 249:6,17 271:14 272:4 Connelly 3:13 9:7 9:7 11:18 14:24 15:1 17:2 19:3 22:19 30:3 36:18 37:17 39:22 40:1 41:1 45:4,11,14 45:22 47:22 48:2 48:12,20 49:1,6,9 51:19 52:1 55:24 56:14 57:5,10	59:3,22 60:20 61:15 62:1 63:8 63:10 65:22 66:2 67:10 68:9 71:19 73:22 77:6 80:16 80:21,24 86:12 86:15,21 89:24 90:8,16 94:12,16 95:23 96:3 98:3,7 99:11,18 100:2,5 100:9 102:22 103:16,20,23 104:2 105:6 106:18,22 109:11 109:17,21 111:16 115:14 123:4,6,9 123:12,24 129:25 130:5 141:3 150:20 153:1 174:17 180:12 209:23 210:2,8 210:11 214:11 216:3 223:19,23 224:6,9 229:17 241:10 247:13 260:24 262:12 263:17,24 264:14 264:17,21 265:1 265:4,11 267:8 267:23 268:9,11 268:18 270:2,7 270:14 272:14,25 273:6,19,23 274:5,8,14,21 consensus 21:24 219:24 consequence 236:5 Consequently 83:8 considerable 53:18 141:4 147:16 192:19 considerably 96:13 152:22 considered 35:9 70:20 92:4 107:20,21 108:24 126:21 138:11,12 245:5 considering 59:4 consist 40:11	consistent 78:24 consortium 145:19 consultant 101:20 consumer 36:6 39:21,25 40:3,7,9 consumers 40:12 contact 83:14 contained 16:20 37:20 73:3 164:25 165:1,1 containing 17:3 72:23 82:1,22 contains 18:2 73:2 content 12:7 202:24 229:2,4 233:7 238:24 239:1 contention 115:24 contents 228:22 238:22 context 44:4 185:12 209:4 continuance 8:10 continue 86:18 147:24 continuing 114:5 contributory 109:5 control 139:20,23 139:24 167:18 187:17 219:6 229:1,3 238:22 238:24 controlled 173:18 197:10 218:13,23 220:9 229:4 convenience 19:23 188:14 convention 160:1 conversation 241:22 conversations 176:11 convey 129:8,9 130:24 131:2,3 132:12 133:24 coordinate 205:4 coordinated 205:7 coordinators 262:3	copied 73:6 copies 107:19 copy 123:17 124:9 141:25 182:21 202:3,6 205:23 216:7 218:10 273:21,22,22 274:18 core 164:10 165:6 165:10,21 166:19 166:21 170:3 172:1 173:21 174:5 175:16,23 176:21 Cornell 4:19 30:12 30:13,19 corner 124:22 232:12 corporation 1:7,7 1:18,19 2:7,8 8:21 correct 12:11 13:13,14 14:10 14:15 15:16,17 15:25 16:4,7,20 16:25 18:11,19 18:22,24 20:1,14 20:15 22:6,18,24 24:4 25:11,13,20 25:25 26:3,4,7,14 26:24 30:1,18,23 31:11 32:7,8,9 34:2,3 36:10 39:20,23 45:3 47:7,13 49:23 50:11 51:24 54:17 55:12 56:20 57:4 58:8 58:13,18 60:15 69:1,16 71:9 74:21 75:22 76:7 77:4,11 79:15 81:9,10,12,18 83:23 84:23 85:22,23 87:11 88:21 91:13,14 91:23 92:13,14 92:17,23 93:11 93:14 100:8 103:1 105:18,19
--	--	--	---	--

- 106:8 108:12,13
139:4 171:25
174:20 184:11
186:11 205:14
212:13,15 225:18
230:10 241:16
243:22 245:15
246:15,18,21,22
248:22 250:24
252:24 254:25
255:1,2 259:4
261:6,12 273:7
275:11
- corrected** 33:9
correctly 24:19
25:15 77:15 78:1
78:2,9 106:2
139:3,5 212:12
correlation 125:23
125:24 126:7
correspondence
84:7
corresponding
84:25
cosponsors 35:12
cost 34:9
costs 34:9 96:20
Counsel 3:12
10:10 49:10 59:3
80:25 90:19
100:11 106:18
110:11 129:25
151:17,20 166:13
166:15,18 213:20
214:17 222:5,9
223:10,14 235:15
267:18 273:10,11
- counselors** 9:2
Counsel's 99:16
count 55:7 57:22
countries 105:23
country 125:25
179:5
County 1:1 2:2
8:14,22 270:6
couple 10:5 54:16
164:7
course 10:25 19:21
53:14 101:15
106:5 131:15,22
- 150:1 258:21
273:8
court 1:1,10,23 2:6
2:18 8:13,17,23
8:24 14:22 260:9
269:18 273:12
274:9 275:2
Covax 131:22
cover 107:11
covered 41:17 97:6
97:7,9 110:11
269:22,23
covering 75:4
97:10 262:7
co-authored
150:15
co-authors 231:11
co-investigator
149:9 179:11
co-investigators
240:2
Co-morbidity
129:15
co-organizers
35:13
co-PI 261:23
co-principal
149:10
co-principle 149:6
CR 233:11
crazy 94:6
created 12:11,12
16:6
criteria 92:6 151:5
151:25 156:24
159:3,4 165:7
259:7,11
critical 168:19
223:23
criticism 248:15
249:2 255:12,20
criticized 246:19
248:14
Cross-Notice
129:21 130:12,13
Cross-Noticed
130:4,9
CSPI 5:24 99:20
CTB 139:22
currently 216:15
- cushion** 264:9,12
cut 174:25
-
- D**
-
- D** 1:13 5:8,13 6:4
243:9
damage 255:19
Darcene 2:4
data 6:24 10:23
11:3 12:20,21
16:20 25:14,22
29:1 32:9 35:21
36:15 38:10,15
39:6,8 41:23 42:3
43:2,4,6,8 47:15
62:5,5 65:15,15
70:9,10 71:4
76:17 78:6 79:14
84:8 85:22,25
93:2 97:25
101:21,24 106:4
115:4,8 116:19
118:6 119:12
120:21,25 122:11
128:3 129:9,13
129:15 132:17
133:1,2 135:8,13
137:2 146:25
163:22,22 167:18
168:1,2,13,17,18
170:12,19 178:18
187:3,19 188:16
188:23 189:10,11
192:20 199:9
204:22,23 205:1
205:5,8 209:16
211:1,3,14
213:12,15,16,17
213:18 214:4
221:19,25 223:4
236:2,23 237:4
237:15,23,23
238:6,11 239:3,7
239:12,22 240:8
250:13 251:3,8
251:12,21,23
258:1 272:1
date 5:3 56:12,17
56:18 105:1
183:10 185:21,23
- 185:24 186:1,5,8
208:20 215:2,6
216:4 217:2,4,6
222:15,16,22
223:23 225:17
227:21 230:13,25
231:1,6 232:4,6
261:8,9
dated 11:19 15:2
18:1 75:12 85:13
104:12 107:4
209:22 215:1
216:8,20 222:24
242:19 275:20
David 74:14 75:6
82:1 94:7 112:13
Davis 3:8 4:5 9:9,9
16:8 17:1 21:19
26:15 27:21
28:21 29:19
32:24 33:4,7
38:16 39:3,10
41:21 43:1 44:2
45:6 46:3,21
47:14 49:24 50:5
50:13,16,22
51:25 54:1,24
55:4 56:25 59:10
61:8,18 62:2 63:1
63:5,9,12 64:23
65:21 67:22 68:7
69:10 75:20 77:5
79:11 80:5 81:1
84:4 87:17 90:3
93:1 94:18 95:6
95:15 96:11 97:3
98:2 99:10,12,17
106:9,21,23
109:9,15,18
110:5,7 111:7,12
111:19 112:1
114:7,17,20
115:7,17 116:1
117:12 118:18
121:15 123:9,13
123:14 124:3,5,8
125:19 126:18
129:23 130:11,18
130:19 132:10
135:20 136:5,19
- 137:22 140:1,20
141:20,22 143:4
143:16 144:13
145:8 148:13,23
150:19,21 153:4
153:5,10,13
155:7 156:1,8
158:8,17 161:7
162:17 164:3
167:1 173:16
175:2 180:6,20
181:9,17 182:6
183:5,9 184:19
186:7 191:11,13
194:21,24 197:19
201:11,22 209:9
209:20,25 210:5
210:15 211:16
212:7 213:14
214:15,16 215:10
215:18,21 216:5
217:5 218:8
219:7 224:15
225:21 226:10
228:1 229:23
230:2,7 235:5
236:9 239:17
240:4,13 241:1
241:25 242:7
246:24 248:9,23
249:4,25 250:9
250:18,25 251:14
252:13 254:6,14
258:5 262:10,20
263:3,12,16,21
264:12,16,25
265:3,10,18,25
266:4,9,16,21,25
267:13,20 268:3
268:7,10 269:12
269:21 270:19,24
272:9 273:3,8
274:6,7,20
day 8:10 82:5
110:1 116:15
158:15 209:6
210:21 264:6,24
266:12 275:20
days 70:19 206:19
211:2,6,12,20

- 212:3 266:13,13
269:20 270:11
274:3
dba 1:7
DD 112:25
deal 120:10,15
234:6 263:14,19
263:20 265:17
dealing 218:11
deal's 263:14
Dear 82:25
death 118:16,19,20
136:22,25 137:8
138:3 167:20
deaths 117:9 137:9
137:12 208:10,13
208:16
decade 106:11
125:11 127:19
131:7
decades 143:25
December 4:22
32:19,24 62:17
112:6 224:1
230:14
decide 244:23
253:6
decided 35:14
53:24 66:13
93:25 108:22
148:7 250:22
deciding 211:11
decision 53:9 94:2
decisions 170:21
decision-making
203:8
declare 160:2,6
253:17 275:17
decrease 126:8
decreased 126:12
127:10
deep 168:7
defects 137:14
Defendant 1:19
Defendants 1:8 2:9
3:7 8:16,21 9:1
111:10,14 112:23
122:19,22 152:24
154:5,23 155:5,9
177:22,25 182:4
182:8,18 193:10
195:19,22 201:24
202:2 212:5,9
217:14 219:14
226:12 229:13
Defendant's 6:7
201:20
defense 268:24
269:5
defined 154:18
249:20
defines 246:24
definitely 94:24
111:17 126:23
259:3
definition 248:16
252:3,8
definitively 127:4
defray 34:9
degree 114:5
deliberately 88:5
249:7
delighted 93:20
delineate 176:3
demonstrating
115:4
Density 206:17
department 4:12
5:23 15:8,11,14
90:17 124:11
184:2,2,4,6
departments 31:3
depends 254:7
DEPONENT 3:11
deposition 1:21
2:13 8:11 9:24
11:14 14:16
17:18 19:1,8
23:11 30:4 32:13
34:20 35:23
37:21 48:17
51:12 62:7 63:13
68:5,22 80:10
81:2 88:9 90:10
99:8,21 103:14
106:14 110:2,23
111:10 114:10,13
122:19 123:16
129:22 130:1,10
152:24 158:16
177:22 182:4,18
193:10 195:19
201:20 212:5
219:14 226:8
229:13 235:16
240:22 242:9
260:1 266:12
267:2 268:2,19
268:22 269:19
270:8,15 273:7
274:23
depositions 130:13
130:15 268:21
depressed 117:25
122:4 134:13
135:16 163:3
164:14,19 165:5
188:16,20,23
197:15 243:9
257:20,25 258:7
depression 6:9
10:2,2,24 11:1,2
35:3,9 44:17 70:3
112:8 113:20
114:24 115:18
118:15,23 122:2
122:3,6,9,16
125:4 128:11,22
129:1 130:22
131:6,14,14,17
131:18,19,20,21
132:16 133:9,15
134:9,13,22
135:2,12,13,15
135:18 136:10,13
138:17 142:24
143:21 144:2
145:18,19 146:17
146:23 151:5,8
152:9,10,16,18
152:21 154:1
156:19,21 157:2
157:4,6,9,17
159:25 160:10
163:25 164:1,9
164:10,23,25
165:2,12,24
166:1 168:21,24
169:8 170:2,10
172:3,8,12,18
173:3,19,23
174:7 175:18,25
176:15,18 177:18
179:22 180:2,16
181:12 185:19
186:24 187:25
188:3,5 193:4
195:6,11,17
197:17 203:6
206:22 207:18
225:7,8,10
227:10 243:11
245:2,2,3 246:14
256:16,17,22,22
257:1,4,6,7,8,11
257:12,13,14,16
257:17,19 258:11
depressions
122:15 129:12
132:19 257:21
depression-related
155:16 248:2
depressive 12:18
14:3,9 20:9 21:9
25:6 31:22 61:4
112:24 113:8
117:22 120:7,18
121:7 122:5,18
128:19 132:2,5
132:23,25 134:15
135:22 139:10
143:8 145:3
147:14 165:6
220:9 253:23
derived 216:16
describe 72:20
75:23 107:16
147:10 149:15
178:8 222:1
described 154:17
157:18 171:23
179:14 200:6
206:5,20 247:3
256:10
describes 13:10,23
describing 10:23
154:11 195:12
205:13,21
description 4:6 6:8
200:2 272:2
descriptions 79:24
205:11,12
descriptive 200:18
deserving 212:4
design 16:18
101:21 147:2,6,7
147:11,24 148:5
148:6,8,9,11
149:20 185:9
197:10
designed 102:9
139:19 143:13
148:17 163:17
167:13 172:15
187:16 190:18
designing 102:3,4
163:14
detail 124:19
183:22 185:10
details 41:11 82:10
194:1,7 204:20
deteriorates 172:9
determine 52:11
59:15 219:10
259:1,8
determined 60:12
60:16 164:5
165:21
determining
192:25 193:3
203:9 259:12
developed 234:8
developing 122:3
devote 255:6
diagnoses 10:25
difference 21:13
65:3,4,13,16
80:23 156:16,17
159:14 171:18
227:11 244:6
246:10,11 269:1
differences 76:12
76:14,22 156:19
244:4
different 10:13
22:13 25:16
26:18 27:1 28:18
31:5,6 45:24 53:6
70:24,24 71:2,6
75:24 76:4,18

77:1,2 79:19
 97:14,18,18,23
 101:9 119:12,13
 127:4 147:1
 164:1,9 175:8,13
 176:16 177:4,7
 189:9 201:1
 208:19 209:18
 211:10,11 230:2
 230:3,3 259:11
 262:21 274:13
difficult 170:9
difficulty 192:8
dilute 265:6
Dineen 226:17
direct 44:17 90:22
 114:2,13
directed 90:19
 100:21
direction 126:21
 126:22 160:5
 169:6,14 170:1,5
 171:15 173:9
 187:6 188:15,22
 189:5 246:3
directional 171:15
 244:13
directionally
 169:10 171:16
directly 82:15
 274:7
director 100:20,22
 100:24
disadvantageous
 189:13
disadvantages
 150:9
disagree 45:1,2,20
disagreed 45:9
 46:5
disagrees 92:24
disappearing
 247:16
disappointment
 44:20
disclose 178:8
 221:5,10 252:23
 253:12
disclosed 234:11
disclosing 221:21

227:18 252:19
discomforting
 28:13
disconfirm 133:3
discontinuation
 211:9
discourage 189:2,4
discovered 83:3
discuss 12:14
 24:11 52:8 55:6
 68:14 89:11 90:3
 104:19 124:18
 149:23 150:1
 198:4 199:15
 201:4 204:15
 216:10 242:21
 254:19 270:20,20
discussed 24:12
 26:17 35:17
 38:20 41:7,10
 42:8 52:9 53:13
 53:21 64:4
 119:16 146:4,10
 147:9 148:21
 150:5 171:20
 172:11 185:9
 198:25 199:2,21
 209:12 210:6
 222:7 223:5,10
 223:13 271:1,9
discusses 13:18
 200:23
discussing 13:20
 171:11 195:11
 202:12 225:9
discussion 14:12
 65:1 72:5,6
 111:21 171:1
 199:20 200:21
 210:18 225:15
 226:5 254:9
 255:7
discussions 43:11
 73:15 150:9
 194:3 224:23
disease 116:19
 137:13,13
disingenuous
 26:11
dismay 69:23 70:1

dismayed 67:20,24
 67:25 69:9,16
disorder 12:18
 14:9 41:8 61:4
 112:24,25 113:8
 113:8 120:7
 131:3 135:23
 145:3 165:6
 167:19 168:14
 204:6 220:9
 225:2 253:23
disorders 33:15
 35:3 113:16
 114:24 115:19
 117:23 120:18
 121:8 131:13
 132:5,5 134:16
 134:20 139:10
 143:8 147:14
 176:17 180:25
 192:17,19 199:7
 204:6 219:24
 226:19
dissatisfaction
 75:15
distinct 229:25
distinguish 190:17
distinguishes
 160:15
distinguishing
 185:1
distorting 266:9
District 1:10,10
 8:17,18,23,24
disturbance 51:10
 175:10 176:8,14
 203:18
division 15:21
doctor 9:19 11:22
 23:14 30:9 44:7
 48:16 49:21
 59:14 67:5,15
 68:25 70:21
 102:20 106:23
 122:21 123:15
 174:15 182:7
 194:21 205:23
 206:14 217:1,24
 218:12 219:17
 225:19 227:24

228:2 229:15
 230:9 233:11
 240:25 262:16
 263:8 267:3
 270:20 272:9,12
doctors 33:17
Doctor's 273:17
document 5:25
 11:23 12:9,12
 15:5,24 17:25
 18:13,15,18,21
 18:22,23 19:12
 19:19 23:15 24:4
 27:4 32:20 36:3
 50:19 51:20 52:2
 62:11,14 68:10
 71:10 72:10,21
 73:21 74:3,18
 76:8 80:14,15
 83:24 86:24
 87:24 88:8,13,19
 90:7,14,15,20,25
 91:2,4,9 93:9
 99:6,7 100:15
 104:7,10,14
 105:9 106:21
 107:1 108:2
 111:15,16,24
 112:2 155:22
 174:19,21 183:7
 193:14 194:19,20
 194:23 196:23
 197:6 210:17,25
 232:15,17 260:22
 260:24,25 261:4
documentation
 85:8
documented
 204:24
Documenting
 197:16
documents 18:10
 19:11 33:2 59:5,7
 72:8,13,14,17
 77:8,12 80:17
 81:14 91:6 230:1
 230:11 242:15
 265:14
document's 31:10
 75:9

dog-eared 212:21
 220:1 227:2
doing 10:12 38:2,6
 43:12 46:11 47:3
 96:19 97:17
 140:18 148:8
 150:10 206:5
 226:6 256:13
 265:12 267:9
 274:12
dollars 95:14,22
domains 175:9
 197:12
Donald 165:25
dosage 13:23
dose 222:18
double 131:14,17
 131:18
double-blind
 227:8
Doug 112:13
downplay 238:10
Dr 8:11 9:8 15:15
 15:20,21 16:14
 17:7 19:8 21:23
 25:17 33:4 50:10
 52:15 53:1,10
 55:17 57:19
 58:17 59:20,25
 60:2 63:1,3 67:2
 67:19 68:11
 69:15,17,25
 70:22,24 72:23
 72:23,24,24,24
 73:15 75:25 76:1
 76:9,24 80:16
 83:12,12,13,19
 84:5 85:1 94:11
 94:18,22 100:19
 100:21 110:2,6
 111:20 112:2,12
 112:13,13 114:21
 114:21 123:11
 129:16,21 130:9
 130:20 141:25
 142:1,3 143:24
 146:11 147:9
 148:24 149:11
 150:15,18,19,22
 153:6 155:8

- 158:16,18 163:20
167:15,15 170:20
174:11,24 175:1
175:3 176:11
180:8 182:24,25
183:19,19,25
184:5,13,13
185:20 186:9
196:2,6 198:12
198:18 201:18,23
202:9,17,19,20
203:7 204:12,20
205:24 209:3,21
210:18,18,23
211:25 212:9,12
212:14,16 213:6
213:22 214:17,20
214:23 215:1
218:12 220:18
224:19 226:13,20
227:17 228:10,11
230:15,17 231:10
231:22 233:1,3
239:19 240:13,22
241:22 242:1,1
242:17 243:18,20
243:22 244:1,24
245:23 246:12,19
248:13 249:2
261:2,22,23
262:1,4,7 263:2
268:20 270:25
272:17,18 273:25
draft 6:19 7:6 75:5
75:14 76:12
88:16 182:15,16
182:22 183:1,2
183:11 184:23
193:17 230:20
231:12 232:8,22
243:5
drafted 263:2
drafts 209:8 229:8
229:11 231:17,19
233:5
dramatically
95:17
dredged 251:2
Drinker 9:12
dropped 94:8
- 126:1
dropping 95:1
Drs 82:3,6 85:12
88:15 145:20
193:6 203:3
drug 61:6 87:12
100:20,22 101:22
109:2 142:22
233:25 259:3,19
drugs 87:8 89:17
drug's 37:14
DSM-4 151:5
dubious 57:19
dude 263:15
Dulcan 6:21 196:2
duplicate 229:22
duplication 67:25
duration 132:1,19
duties 273:13,15
duty 265:13
dysthymia 131:19
256:25
dysthymic 112:25
113:8 131:13
132:5
d/b/a 1:18
d/b/a/GLAXOS...
2:8
-
- E**
-
- E** 3:1,1
earlier 16:25,25
24:12 25:11,15
32:5 35:17 62:19
69:8 198:2
235:16 243:5
earliest 72:18
early 113:7
Early-onset
112:24
easier 10:11 16:21
122:12 128:19
Eastern 1:10 8:18
easy 116:14
ECNP 18:5
edification 15:10
edit 12:8
edited 231:16,19
editor 6:18,23
77:18 112:4,5
- 181:21,25 182:2
182:2 196:3,13
196:17 202:6,8
262:21
editorial 161:16
editors 162:6
248:15
edits 232:10,13
effect 14:2 116:13
120:5 158:5
175:11,12 255:8
effective 14:8
20:20 21:11
22:18 25:8,20
26:3,6,13 32:1,6
34:16 35:18
37:15 40:23
41:14 61:3 62:22
118:7 120:12
138:16 139:2,9
139:15,18 159:24
165:12,23 169:7
172:3 173:22
174:6 175:17,24
176:23 179:21
185:4 193:1
222:2 253:22
265:12
effectiveness
120:13 143:18
170:1
effects 27:17,19,22
64:16 66:8,11
104:12 146:5
150:6 203:5,9,15
204:8 206:9
efficacious 116:10
120:6 144:3
181:4,11 220:8
254:11
efficacy 13:16 25:2
26:9,22 31:15
41:4,6 43:18
49:22 50:10 52:9
52:12 54:17,20
55:3,17,21 56:2
56:23 57:7,15,18
57:23 58:1,5,7,11
58:12 59:15,18
60:7,12 67:7,16
- 70:4,8 138:6,25
139:21,22 142:21
143:15,23 144:2
145:1 147:12
148:17,22 154:11
154:15 155:19
156:3 157:12
160:15 163:17
166:20,22 167:3
167:16 169:19
171:23 177:16
178:8,13 179:14
179:25 180:14
181:23 182:11
188:8,13 189:18
190:3 191:1,8,16
191:18 195:4,6
195:16 197:14,17
197:21 198:24
221:5 225:16
227:19 237:4
238:11 239:4
241:13 244:2
247:9,23 250:21
252:18
efficient 10:12
effort 82:15 96:21
147:11 221:9
efforts 95:4 96:1,9
96:12
eight 241:13
either 34:11
140:16 146:7
156:25 169:6
173:19 174:4
189:5 190:12
208:19,23 224:14
240:8 241:22
247:4,8 259:3
263:20 264:19
273:16 274:6
elaborate 79:18
Eligibility 151:1
eligible 151:21
elucidated 185:7
embedded 45:15
embeds 45:22
Emergence 91:18
emergency 117:18
emergent 207:15
- 207:24 208:2
emotional 200:3,5
200:7,12,15,18
200:24 201:2
202:14 203:17
emphasis 246:16
emphasizing
128:20
employed 228:16
employee 111:2
142:3 178:12,16
236:22 237:3
275:14
employees 198:4
198:22 224:24
226:5 234:16
Emslie 5:12,14,16
72:24 74:13 75:6
167:16 170:20
220:11 242:2
Emslie's 167:15
enclosed 231:12
encourage 189:8
encouraged
196:16
encouragement
203:4
encouraging
192:12
ENCP 4:16
ended 98:16 105:2
Endogenecity/m...
133:21
endogenous 134:4
endpoint 153:25
163:6 248:4
endpoints 185:17
186:22 189:22
190:4
endpoint(s) 188:9
ends 166:10
end-point 156:24
157:3,4,5 158:25
160:20 162:10
271:6,9
end-points 41:20
42:10,24 142:21
143:22 144:5,18
153:19,22 154:10
154:16 158:20,24

- 159:18,22 160:11
160:16 162:19,22
163:9 169:21,22
169:23 189:18
249:20 250:6
271:14 272:3,5
Engh 2:4 8:25
enrolled 104:22
151:22 152:14,18
enrolling 104:25
149:17
enrollment 105:2
entered 107:15
entering 9:11
enthusiasm 53:18
entire 41:2 90:15
242:2
entirely 12:5 55:7
137:21
entirety 51:16
197:25,25
entities 97:23
entitled 13:11
48:20,22 67:7,16
82:4 134:15
151:1 154:15
155:19 205:25
219:21 226:17
242:18 261:4
entry 151:25
Epidemiology
128:25
episode 122:12,13
122:18 125:4
128:19 132:7,23
132:25
episode(s) 132:2
equal 154:2,2,19
154:20 163:1
165:10
equally 126:17
equivalent 147:18
Erica 81:25
errata 274:9
erratum 86:1,3
error 79:9,14 86:9
errors 272:19
ESQUIRE 3:4,8
3:13
essence 164:9,10
- essentially** 126:10
135:11 138:3
148:7 187:10
257:3 262:6
establish 138:6
142:21 227:23
established 54:14
57:14 143:23
179:21 190:16
establishes 235:3
Estate 1:12
Esteban 9:11
estimate 25:22
97:15 103:10
198:9
estimates 213:4
et 8:15,16,19,21,25
9:1 116:12 118:3
118:4 185:24
186:13 194:11
202:8 203:7
204:11 220:11,12
220:14,16 221:1
226:24 228:23
229:2 232:24
233:5 239:21
240:6
Europe 183:21
evaluate 97:25
101:21,24 163:9
164:5
evaluated 101:23
evaluation 6:24
100:20,23 157:12
171:23 205:25
233:25
evaluations 154:12
event 86:25 205:20
205:21 259:2
events 64:21 71:14
76:20 78:15 79:2
79:3,5,21,22,25
80:3,8 82:8 83:4
83:7,10,22 84:2
92:4,6 105:10
199:2,5,6,16,21
200:22,23 201:6
202:12 204:13,15
205:6 206:5
207:6 208:21
- 211:2,6,12,18
213:7 215:4,13
216:23 219:10
everybody 121:21
170:12,13,15
267:11
evidence 17:3 27:1
37:21 45:12,23
45:25 46:2 89:25
94:13,17 98:8
100:3 118:13
126:20,22 127:6
127:8,13 128:18
139:25 143:14,17
168:8 170:17
172:5 175:11
177:16 179:25
180:5,14 188:13
195:16 215:15,25
217:1 223:17
228:20 235:6,10
235:23 254:11
exact 69:14 179:15
268:2
exactly 87:6
examination 4:3
9:17 54:12 110:4
114:3,14 212:4
270:23 275:8
examine 212:2
examined 9:15
example 167:23
177:4 200:4,11
200:16 204:3,6
examples 200:7
exceeds 114:2
excellent 195:10
exception 51:16
263:1
excited 189:5
excitement 172:16
exclude 211:12
excluding 222:15
222:19
exclusively 33:18
excuse 32:24 58:10
141:24 142:11
166:14 178:6
215:18 223:11
271:3
- exercise** 59:14
exhibit 6:7 11:14
11:17 14:16
17:18,22 19:1
20:23 23:11,14
30:4 32:11,13,16
34:20 35:23
39:14,17 50:15
51:12,15,19 62:7
62:25 63:5,13,17
68:4,5,9,22 69:3
74:4,11 76:9
77:13 80:10,14
80:16 81:2,6 85:3
88:9 90:6,9,16
99:8,18,21,25
100:5,15,16
103:13,14,21,22
103:24 104:2
106:14,17 111:7
111:10,14 112:23
122:19 123:10,16
124:9 141:24,24
141:25 150:14
152:24 153:1
154:5,23 155:3,5
174:10 177:22,25
182:4,8,18,21
183:3,24 193:10
193:13 195:19,22
201:20 202:3
205:23 210:1
212:5,9 214:9
216:7 217:14
218:10 219:14,17
222:13 225:12
226:8,12 229:13
229:15 230:5,12
230:13,22 232:2
232:4 241:7
242:9 246:24
247:1 260:1,4
exhibits 4:6 69:1
81:8 122:22
153:7 209:24
223:2 230:8
241:1,5
exist 71:18
existed 89:5
134:10
- existence** 38:24
expecting 192:14
expenses 96:15,19
experience 117:17
117:21
experienced 201:2
203:15,16 206:11
experiences 28:13
experimental
184:7
expert 58:23 59:17
59:22,24
expertise 211:23
experts 166:1
explain 71:5 76:22
77:1 78:12
105:20 128:14
190:21
explanation 71:2
76:17
explantation 82:20
explicitly 185:6,8
exploration 53:15
explore 175:20
expressed 58:15
65:18 73:18
76:15
expressing 214:3
extent 67:24
171:10
extract 153:2
extracted 152:2
extrapyramidal
27:7
extreme 201:7
extremely 76:11
e-mail 4:14 5:8,9
5:11,13,15,17,19
5:19,21 6:2 7:7
18:1 19:14 63:1,3
72:22,23 73:2,5
74:12,25 75:4
76:9 81:25 82:1,5
82:7,20 84:6,11
85:12 88:14
174:11,21 175:1
175:5 182:24
183:10 214:25
217:7 232:17,20
242:17

e-mailed 18:23	154:23 185:15	214:6 242:2	firm 110:8 130:13	275:18
e-mails 68:13	186:20	245:1 246:5,13	first 13:10,21	forgetting 35:14
69:15 72:6 78:16	fairness 269:21	fight 269:10	20:12,13 24:10	125:23
81:16 259:11	faith 71:4 76:5	figure 224:11	37:19 39:4 44:15	forgot 243:10
e.g 116:11	fall 250:15	figures 129:14	51:1,24 52:16	forgotten 222:21
	falling 188:14	file 1:25 8:24	68:4 74:4 79:7,16	form 16:8 17:1,2
	false 95:17 126:15	273:24	81:21 85:6 86:9	19:7 21:19 22:19
F	126:17	filed 110:8	107:11 112:22	26:15 27:21
faced 163:13 170:9	familiar 57:21	files 71:25 72:9,11	118:12 120:25	28:21 29:19
facilitated 116:15	90:25 91:2,4	72:14,16 74:14	122:1 124:21	38:16 39:3,10
fact 16:11 19:8	116:2,5 127:14	74:19,21 75:8	131:4 133:6,8	41:1,21 43:1 44:2
36:19 37:20	161:8,17	81:11 88:21	138:1 153:10	45:11 46:21
41:24 44:19 48:7	far 41:17 42:8	183:1	163:2 167:15	47:14,23 49:24
53:20 58:21,24	172:11 183:8	final 5:3 6:5 51:15	176:5,10 177:14	50:5,13 54:1,24
61:4 69:14,21	fast 261:24	63:10 107:10	182:16,22 183:2	55:4,6,24 56:25
75:23 76:23 78:4	favor 46:15 50:4	184:23,24 209:8	183:23 190:11	57:5 60:20 61:8
78:8 89:25 94:13	52:14 53:2	222:17,22,24	194:5,16 195:2,4	61:15 64:23
98:8 109:1	190:12 242:25	223:14 224:16	195:6,15 199:25	65:21,22 67:10
116:16 118:24	245:18 250:7	261:5,8	200:1 203:1	67:22 69:10
119:6 120:3,3,5	FDA 38:22,23	financially 97:10	208:4 211:8	75:20 77:5,6
142:19 144:17	67:25 85:7 89:22	275:15	212:2 214:25	79:11 80:5 84:4
169:13,17 170:3	90:18 91:6 92:24	find 37:9 38:8,19	216:12 224:20	87:17 89:24 93:1
173:8 191:14	93:4,10 100:23	60:8 82:16 123:9	231:17,19 247:25	94:12 95:6,15
219:9 221:13	101:5 125:21	139:17 168:2	248:20 253:7	96:11 97:3 98:2,3
222:1 223:18	142:3,14 143:25	170:11 187:7,9	260:5 263:5	106:9 114:8
235:20 250:21	167:23,23 190:7	187:11,13 189:3	273:17,17	123:25 241:25
255:7	190:13 208:16	191:18 213:8	first-hand 59:6	248:9,23 249:4
factor 175:6	210:19,24 212:10	220:12 221:6	five 40:3 113:18	250:25 251:14
factors 51:5	212:16,18 215:3	246:9,10	115:6 128:22	252:13 254:6
203:23	215:11 216:8,12	Finders 184:4	206:13 230:1	258:5 263:3
facts 45:12 172:4	216:20 224:22	finding 78:23	267:20,24,24	format 12:6
215:25	233:15	92:10 126:6	269:5,5,8,11,12	243:13,13
factual 45:14,23	features 166:19,21	167:16 197:18	270:16 272:16	forth 22:9 109:9
faculty 22:10	February 4:24	244:5 271:22	five-plus 88:2	142:22 157:15
30:18	35:4,10,20 90:18	findings 116:12	five-year 257:23	158:19 159:21
fail 189:3	93:10 218:4,7	170:7 177:15	fix 180:7 230:4	160:9 192:15
failed 26:14,17	231:1,7	179:14 180:13	fluoxetine 167:16	197:22 268:6
41:18 42:22	Federal 273:2	198:24 236:10,14	220:12	forth;at 275:4
43:24 47:1,5 50:3	feed 196:12	237:5	focus 111:21	forward 52:18,22
55:19 60:8,13	feedback 196:13	fine 10:11 19:18	focused 210:19	53:5 55:20 73:2
144:2 188:9	196:21,25 198:1	23:5 29:16 41:7	focussed 211:2	274:1
189:18 190:4	232:14,21,23	44:14 45:17 46:4	fold 117:8	found 51:18 135:9
220:11 221:6	feel 37:24 83:14	48:14,15 49:5	folks 174:22	185:3 188:12,17
247:7	185:4	54:12 55:14	followed 149:19	190:25 244:7,19
fair 43:7 93:19	feeling 28:4,10	67:12 80:13	following 107:9	246:4 250:6
121:4 122:23	Feelings 28:5	85:14 86:3 96:6	175:6 211:9	foundation 16:9
155:9 158:4	fell 85:10 200:23	98:11 250:5	follows 9:16	21:21 79:12
177:25 217:18	felt 172:21	finish 44:10,12,14	follow-up 263:12	125:16 135:25
232:1 248:18,19	field 10:23 170:13	finished 224:17,17	Fong 82:2,6	141:14,16 143:1
251:4	180:22 187:24	finishes 115:15	foregoing 275:3,11	144:9 145:5
fairly 43:6 154:6				

162:12,13 163:12
 172:5 211:22
 215:9,24 235:2
four 13:21 43:22
 46:13 50:10,24
 51:1,3,4 52:9,12
 52:25 53:8 54:3
 55:17 57:17 58:1
 83:7 138:1
 162:18,22 164:4
 164:7 167:3
 169:23 175:6,8
 181:24 229:25
 241:15,18 248:4
 250:6
fourfold 116:18
 119:8
fourth 8:23 14:3
fraction 97:5,6
 165:14
frame 211:6
frames 268:2,5
free 37:24 83:14
 90:15 165:16
 205:20
frequently 93:24
friends 113:22
 136:12
front 162:21
 206:15 224:4
 261:9 267:11
fulfilling 151:5
full 63:7 97:12
 107:20 109:13
 199:25 200:1
fuller 82:19
fully 107:14
full-time 147:18
function 172:18
functioning 113:21
 113:22,23 133:23
 134:12 136:10,11
 136:11 171:3,6
 171:21 172:9
 173:15,20 256:19
fund 34:7 147:21
 148:1,8
fundamental
 37:19 148:5,6
funded 33:25 34:4

178:21 179:12
 206:22 207:19
 245:12
funding 179:7
funds 179:4
funny 270:14
further 74:20
 101:22 102:4
 113:25 114:9
 176:4 232:9
 240:14 263:11
 275:13
future 122:12
 128:13 173:12
 177:3 244:21

G

Galveston 4:12
 15:8 22:11
 123:18 124:11
gathering 22:5
gauged 268:1
general 1:3 2:4
 3:12 69:19 135:7
 135:18 138:2
 143:11 180:21
 253:9 256:14
generally 10:19
genesis 145:17
Gentlemen 270:2
GEORGE 3:4
GEORGIA 3:9
Gergel 198:19
gestures 200:19
getting 37:18
 78:16 85:25
 131:21 166:10
 192:15,18 224:1
 224:7 246:2
ghost-wrote
 228:16
Giles 163:20
Gittleman-Klein
 145:21
give 15:6,18 34:10
 38:14 40:16,21
 43:7 60:25 84:21
 95:13 105:4
 169:5 200:16
 209:18,18 221:17

253:24
given 10:1,4 13:24
 32:5 44:1 119:13
 163:24 229:15
 256:14 258:11
giving 41:11 42:1
 44:9 59:24 72:1
 84:21 108:23
 117:24 118:23
Glaxco 101:20
GlaxcoSmithKli...
 238:9
GlaxoKlineSmith
 110:7 236:21
GlaxoSmithKline
 1:7,18 9:10 111:2
 145:11,14 146:9
 147:20,20,25
 178:11,16 198:22
 205:4,7 206:23
 207:19 208:15
 215:3 216:11,22
 221:20,24 224:24
 235:7,11,19
 237:2,10,17,22
 238:4,22 240:7
Glenwood 8:6
global 14:2 20:8
 21:8 25:5 31:21
 151:13 157:7
 163:5 165:20
 166:2
go 14:6 17:11
 19:19 20:22 23:6
 24:2,20 27:3
 29:25 32:11
 33:17 34:19
 35:22 43:21
 44:14 46:24 47:2
 49:12 54:18,18
 61:2 62:25 63:16
 67:13 72:17
 73:21 74:2 75:3
 81:6 84:23 85:7
 85:21,23 109:9
 109:13 111:9,20
 113:24 119:23
 124:7 131:13
 138:21 161:3
 163:21 165:2

187:23 189:21
 190:6 197:7
 201:11 236:20
 244:12 248:18
 251:5 253:4
 263:20,25 265:21
 266:24 269:18,25
 270:2,3,9 273:16
goal 170:12
goes 68:7 244:3
 264:7 274:11
going 10:8,12
 17:13 37:17
 39:13 49:2,14
 54:21 60:4 65:19
 66:21 68:13,17
 86:16,18 88:8
 94:22,24 101:17
 103:16,25 109:10
 109:22 111:5,13
 111:20 114:4
 122:21 123:15,24
 124:6 141:12,13
 158:9 168:1,16
 172:24 177:13
 182:7,20 187:5,7
 193:12 194:17
 195:21 197:6
 201:13,23,25
 202:2 209:11
 216:19 219:16,22
 240:15,17 253:11
 263:25 264:1
 265:1,4,16,23
 266:18 267:1,16
 267:18,23 268:13
 269:4 272:11
 273:12,15,20,21
 273:22 274:2,4
good 8:3 9:19,20
 10:15 18:3 71:4
 75:3 76:5 79:16
 89:15 94:1 110:6
 124:6 146:16,20
 163:22 169:9
 173:9 190:7
 192:13 236:5
 242:3,8 244:21
 255:6,8,19 256:3
 256:6,7,9 264:22

271:23
good-faith 82:15
Goosner 100:24
gotten 97:16,17
Graham 74:13
 75:6
grand 4:11 15:7,10
 22:4 23:16 30:11
 30:16 31:4
 123:10,18 124:10
Grant 2:15
great 18:25 24:8
 30:7 63:19 93:24
 168:13 190:25
 234:6
greater 137:12
 154:2,20 159:5
 192:11 255:25
Greenberg 116:12
Greg 2:4 232:25
 233:1,1
ground 235:2
grounds 101:12,18
 126:14
group 27:11,15
 39:21,25 40:3,7,9
 53:17 69:16,23
 70:1 83:8,18
 85:11,16 87:16
 102:10,12,15,16
 102:19 136:4,7
 148:22 171:8
 203:10 206:18
 211:15 256:6,7
groupings 213:5
groups 119:13
 227:12 256:6
grow 135:12
grown 135:16
GSK 16:16 36:23
 37:15 38:2,6,14
 39:2,5 51:20 58:3
 59:16 64:7,9
 65:18 66:15 67:7
 67:16 69:9 70:2
 78:17 79:10 80:7
 82:7,23 84:18
 85:25 88:15,18
 93:5 96:9,23
 97:24 98:15

101:20 129:21
130:4,9 145:13
174:22 198:4,13
208:18 215:11
224:25 226:5
245:9
GSK's 80:4,6
guarantee 85:2
guess 23:23 150:12
254:7
guidelines 234:2
235:8
guys 109:19,20
124:4
G-O-O-Z-N-E-R
100:24
G.Clarke 7:7

H

half 86:19,20
95:14,21 106:20
113:17 144:1
248:20 255:25
266:2
Hamilton 151:7
152:6,9,16
153:25 164:24
187:25 245:2
246:8,14
Hamilton-D
156:23 157:1,3,7
158:25 163:1,3
164:19 165:9
175:6 247:4
Hammad's 213:6
Hammand's
213:22
Hammond 212:12
212:14,16 217:8
217:10
HAM-D 51:4,7
151:21,24 152:1
154:1,3,4,19,21
154:22 157:2
159:2,6 164:14
188:1,19,20
241:19,23 242:3
242:21 243:8
244:4,6,15 247:5
247:6 249:12

hand 111:5,13
122:21 123:15
141:23 150:13
155:2 182:7,20
193:12 195:21
201:23 205:22
212:8 218:9
219:16 222:12
226:11 229:18
handed 153:6
handing 174:9
handle 86:8,9
handwriting
230:16,17
handwritten 232:4
happen 267:1
happened 79:24
107:16 207:6
266:10
happening 121:5
happens 134:25
135:5,7 235:17
happenstance
219:5
Harbor 4:24 35:4
35:9
Harborside 30:15
hard 117:9 234:13
258:20
harder 191:18
244:6
harm 70:16,17,18
70:20,20 75:19
118:25 206:17
255:5
hazard 113:19
126:8
headache 203:15
204:8
heading 169:25
health 5:23 77:21
83:16 90:17
171:3,7 178:23
179:1,2,4,8,13
214:19
hear 49:9
heard 40:2 252:10
252:14 256:21
heart 137:13 173:2
HEDLUND 3:4

Heh 243:1,3
held 11:25 101:5
267:4
help 69:7 187:4,8
196:17 214:12,21
215:6 217:21
264:8
helped 164:20
262:25 263:4,5
helpful 34:13
105:4 136:6
170:18
helping 73:25
Hennepin 2:2 8:23
Hey 55:2
Hi 18:3
hidden 197:22
hide 160:18 238:10
high 122:3 161:22
191:3,5,14,17,23
191:25 192:5
220:13
higher 118:17
129:17 134:19
136:14,17 152:23
157:6
highlight 116:8,8
highlighted 80:25
112:20,22 121:24
122:1,24 220:2
highlighting 80:18
80:18,23 111:17
111:19
hiring 96:20
histrionic 134:20
hit 189:23
hoc 252:24,25
253:1,9,12,14
hold 70:11 143:5
143:10 264:19,23
265:16
holds 233:25
home 113:21
136:11 243:15
homicide 137:4
honorarium 34:10
hope 88:16 93:24
265:11
hospital 117:10,11
184:4,8

hostility 200:10
hour 86:16,19,20
106:20 109:13
266:2
hours 263:18
264:5,8 266:2,14
269:2,2,23
Huh-huh 27:5
64:19
human 90:18
256:12 258:21
hurt 264:12
hypothesis 28:25
54:13 177:3,7
190:24 251:7
253:1
hypothesizing
28:23
H-D 243:8

I

idea 94:22 145:17
idealization 75:19
ideation 70:17,19
71:13 83:6
131:25 200:19
203:17 207:16,25
208:2,3,6
ideation/gestures
200:8,16
identification
11:15 14:17
17:19 19:2 23:12
30:5 32:14 34:21
35:24 51:13 62:8
63:14 68:6,23
80:11 81:3 88:10
90:11 99:9,22
103:15 106:15
111:11 122:20
152:25 155:6
177:23 182:5,19
193:11 195:20
201:21 212:6
219:15 226:9
229:14 242:10
260:2
identified 83:7
141:17 157:10
234:9

identify 9:3 11:22
15:5 17:24 19:10
23:14 30:9 32:15
34:24 36:2 62:13
88:12 100:17
104:6 106:25
153:19 154:10
160:9 226:13
242:14
idiot 42:16
ignoring 229:21
II, Deceased, and
1:12
Illness 5:2 36:6
illnesses 12:19
113:1,9
imagine 53:12
imipramine 13:25
14:4 20:17 21:10
25:7 31:23 87:15
87:22 89:16,19
147:13 152:3
155:18 156:18
164:22 165:11,23
168:23 171:5
175:17,24 231:11
immaterial 97:10
Impact 171:21
173:19
impairment
113:21 125:5
133:22 135:21
136:2 167:20
172:14
impartial 94:5
impedance 192:17
implementation
149:22
implementing
149:17
implication 88:4
implications
185:11
importance 122:6
122:7,9 164:5
196:18
important 39:8
43:17,24 62:5
66:6 124:25
125:2 128:9,21

- 146:13 163:8
166:5 168:3
170:8 172:21
173:1,4 197:13
197:18 221:19
236:2 258:15,18
impressive 244:7
improper 141:18
252:17,21,22
270:9
improperly 178:17
improved 171:9
173:7 193:4
improvement 14:2
20:8 25:6 31:21
44:18,19 145:2
165:21 166:3
168:23 172:13
175:14 255:24
improvements
21:9 171:7
improves 172:12
inaccurate 94:10
inadmissible
194:20
incidence 206:17
207:15 218:21
incident 218:25
include 10:5 41:10
62:21 156:2
172:22 196:16
199:5 200:19
206:9,25 207:17
207:19 209:15,15
211:12 257:8
included 11:3
23:19,22 47:6
55:22 56:23 57:6
59:16 83:11
92:11 134:4
200:5 208:21
includes 200:25
including 23:19
29:22 41:8 55:17
96:16 117:14
134:20 141:6
147:9 170:13,15
194:5 197:9
202:13 203:16
208:17 213:18
238:12 256:7
271:12 272:1
inclusive 1:8
incomplete 100:9
incompletely
236:1
incontrovertible
135:11
incorporate 16:11
incorporated 16:5
16:10 232:13
incorrect 47:11
incorrupt 16:11
incorporated 16:5
16:10 232:13
incorrect 47:11
58:2 65:8,10
84:22 185:4
250:24
incorrectly 138:23
138:24
increase 120:16
127:9 131:25
133:23 236:6,11
increased 92:3,8
116:18 119:8
126:11 132:6,23
132:24 199:10
207:8,24 208:24
213:9 216:14
increasing 120:3,9
236:24 237:19
239:13,23 240:10
independent
105:24
Index 116:20
indicate 73:1 76:24
87:15 173:13
192:23
indicated 70:8
72:15
indicates 173:11
indicating 185:17
186:23
indication 191:1
206:18 225:1,1
indicators 14:13
individual 105:16
105:17 136:2
140:13 213:1
258:16,18
individually 1:11
1:13,14,15 174:4
Individually;Ch...
1:15
individuals 73:4
184:10 202:18
industry 64:7
238:20 245:12
industry-sponso...
220:14
ineffective 142:23
inflection 137:5
influence 178:12
178:17
influenced 98:23
influences 98:21
influenza 137:14
inform 66:7
221:15
informal 128:17
information 5:25
7:11 43:25 61:14
61:25 63:24
71:11 82:12,18
84:14,20,22,24
85:20 96:22
102:21 105:3
129:7 130:24
133:24 168:19
169:5 170:8,14
170:21 177:2
216:15 221:14,21
241:2 258:14
informative 165:4
258:23
informed 58:23
66:10
informing 106:2
Inhibitor 203:11
inhibitors 121:21
126:11 138:15
220:7
initial 91:19
147:19
initiated 146:22
injury 83:5
input 202:24
228:22 233:6
inputs 232:1
inquiry 214:18,20
214:22
insist 264:22 265:1
267:4
install 259:19
Institute 178:23,25
179:2,4,7,13
institutes 179:3
Institutional 104:9
105:25
INSTRUCTED
7:9
instruction 61:17
instructions
274:15
instrument 244:25
245:15,17 246:4
instruments
164:12 192:23,24
192:25
insufficient 141:5
141:9
insufficiently
185:1
Integrity 100:24
intend 59:18 214:2
intended 59:25
176:5 214:1
235:19
intention 235:24
235:25 271:19
intentional 83:5
interactions
175:13 234:17
interest 93:23
101:1 172:21
173:2 234:10
interested 40:19
203:8 275:15
interesting 31:6
59:4 176:19
258:21
interests 111:22
211:7
internal 28:6 88:18
Internet 103:17
interpret 169:17
169:24 173:11
178:13
interpretation
80:1 211:4
interpreted 185:15
186:21 194:11
interrelationship
126:5
interrogatory
95:19
interval 96:17
109:6 209:16
226:4
interventions
113:3
interview 163:5
introduction 126:2
138:14 195:10
Investigative 8:5
investigator 6:6
79:10 121:2
149:6,9 179:10
207:5 226:21
239:10 240:5
261:5
investigators
16:17 35:2,8 54:9
80:4 83:1 145:10
146:8,10,12
147:24 148:15
163:8 164:21
198:4 204:7,14
205:4 229:10
239:20
invitation 15:6
invite 15:11,18
31:5 35:15
invited 15:21 31:2
35:11 40:16
236:19 237:8
involved 82:9
147:2,7 174:2
204:14 207:4
208:22 213:21
241:21
involvement
110:10 147:5
149:16
involving 92:9
174:3 237:24
241:23
IQ 151:16
IRB 104:11 105:20
105:21 107:3,5,7
107:8
IRBs 108:21
Ireland 4:18 23:17

irrespective 121:8
isolation 169:17
issue 5:3 26:17
 29:3 53:14 69:20
 70:1 76:6 89:23
 116:4 131:2
 148:8,9 153:2
 244:3 269:22
issues 86:12
 120:14 148:11
 226:6
italicized 246:17
item 157:4 163:2,4
 164:15,15,19,20
 164:25 168:21
 188:20 243:9,11
items 164:25 165:1
 165:1 170:4
Ivan 198:18
I-N-D-E-X 4:1
Le 248:6

J

J 4:14 7:4
JAACAP 6:11,12
 6:13
JAMA 254:15,19
 254:19
Janet 100:19,21
January 99:19
 107:4 142:1
 209:13,22 222:20
 223:11
jargon 176:25
Jetter 77:17,17,24
 83:16
Jetter's 77:20
Jim 18:1 54:15
 55:1 82:2 231:15
 231:16
Joan 112:14
job 79:16 80:2,6,8
 190:7 195:10
 271:23
John 139:16
join 46:3 59:10
 61:18 90:3 141:3
Joined 62:2
joint 85:10
jointly 24:16,17

journal 112:4,5,17
 112:18 156:4
 160:25 161:10,11
 161:13,15,20,24
 162:2,6 182:10
 183:15 186:12
 193:16,24 194:5
 195:24 202:4
 217:19 219:20
 220:21 221:14
 233:23 254:20
journals 45:10,21
judge 114:16
 196:17 219:3
 263:25 264:7,7
 269:10 270:5,21
judged 204:7,9
judgement 166:5
judges 270:22
Judicial 8:23
juice 190:12
July 4:12 5:2 15:2
 15:8 36:8 123:19
 124:12 185:25
 222:24 223:14,25
 224:2,17

June 216:8,20
Jureidini 183:17
 183:19,25 184:13
 186:9 193:6
 242:18,19 244:24
 245:23 246:13,19
 248:14 263:2

Jureidini's 249:2
jury 28:2 81:23
 105:20 125:1
 128:14 129:4
 131:11 133:19
 164:15,16,17
 166:9 174:14
 178:2 200:6
jury's 15:9 121:16
 174:10 184:20
 205:16

K

K 5:18
Karen 74:13 75:7
 76:10 226:13,17
 243:3

Kaufman 112:14
keep 13:3 23:23
 150:11 162:20
 248:5 273:21
Keller 5:8,10,11,13
 5:15 6:2,14,15,16
 6:17,21 16:6,14
 16:24 17:7 21:18
 21:20 24:13
 25:17 65:18
 67:20 68:11
 69:15,17,25
 70:22,25 72:23
 73:16 74:12 75:6
 75:13 76:1,9,24
 82:3,6 83:19 84:6
 85:1,12 88:15
 118:3,4 145:20
 146:11 150:15,18
 150:19,22 153:15
 154:9 182:24
 185:24 186:13
 194:10 202:8,9
 202:13,20 203:7
 204:20 214:20,23
 215:1 220:11
 221:1 226:24
 228:23 229:2
 231:10,22 232:13
 232:24 233:5
 239:10,21 240:6
 241:22 242:1,17
 243:18,20 244:1
 247:14

Keller's 19:8 21:23
 75:25 204:11
 230:15,17
Kelly 243:23
kept 116:2
Kessler 129:16
kid 117:10 168:12
kids 61:6 85:8
 89:23 113:20
 117:18 118:16
 166:7,7 168:12
 171:16 257:22,24
 258:3,10

kill 109:2 262:17
killed 258:4,7,12
kind 141:9 169:11

273:3
kinds 23:19
KING 3:8
Klein 165:25
knew 36:16,17,25
 37:10,11 88:2
 146:24 217:2
 221:18
knock 266:6
know 13:19 15:13
 15:22 16:13 31:3
 37:10,11,13 38:3
 40:2,10 43:13,21
 44:22 49:1 50:2
 53:13,23 54:6,8
 56:1 58:21,23
 59:1,1 60:16
 65:24 69:11
 72:10,13 75:1
 80:24 84:14
 85:18 87:12,19
 88:1,18 97:5
 98:24 102:10,11
 102:12,20,21
 103:9 105:5
 106:11 109:4
 110:14 116:6
 120:13,13 125:6
 125:12 126:23,24
 128:7 129:18
 133:2 139:21
 147:16 148:10
 150:3,6 152:22
 160:7 168:11
 172:6,10,11
 179:9 189:10,20
 194:10 196:9
 197:1 205:9
 212:3,17 214:25
 217:4 219:4
 223:17 224:11,12
 229:8,12 249:6
 249:10,10,14
 251:8 253:16,20
 254:4 257:21
 265:17 269:21
knowing 254:4
knowledge 14:11
 17:7 28:24 29:20
 36:24 37:24

38:25 59:6 60:1,2
 66:15 71:22
 75:10 79:17
 81:15 86:4,5
 89:18 98:18 99:3
 109:3 135:10
 181:10 216:4
 224:21 245:10,12
 250:11 259:14
known 27:20 34:1
 36:10,20 37:4
 62:6,17 99:20
 101:17 122:10
 133:1 164:11
 174:1 180:21
 226:24

knows 37:15
Kohar 2:17 275:2
Kong 82:24
KYLE 1:12
K-SADS 243:11
K-SADS-L 157:3,6
 163:4 164:15,19
 164:25 168:21,24

L

lability 200:3,5,7
 200:12,15,18,24
 201:2 202:14
 203:17
lack 76:17 125:15
 135:24 141:14
 142:25 143:18
 144:9 145:5
 162:11 163:11
 211:22,22 215:8
 215:23 235:2
lacks 172:5
Laden 182:25
 228:15 229:1
 262:24 263:4
lag 172:13
lags 44:19
laid 141:16
language 128:17
large 12:1 36:13
 95:5,12 96:9
 148:9,11 150:9
 179:4 197:9
larger 10:6 11:2

44:4 47:12
 149:20,21 179:11
 192:17,18
lasted 113:16
lasts 136:12
late 123:24 264:13
Laughren 142:3
 210:10,19,23
 211:25
Laughren's 142:1
 209:21
law 110:8 272:23
laws 275:17
lawsuit 110:7
lawyer 111:2
lead 83:19 204:21
leading 118:1
 132:9 135:3
 137:8 180:5
 191:9 215:14,24
 218:5,24 234:4
 235:22 272:7
learned 224:20
Learning 3:13
leave 10:13 14:24
 236:19 269:24
lecture 15:19
 253:24
lectures 60:25
led 139:16
left 28:20 49:23
 50:3 264:6
 269:11
left-hand 124:21
 232:12
Leigh 2:4 8:25
length 173:6
Lensing 2:4
lesser 171:10
lethal 117:7,16,20
 119:2 134:10
lethality 116:14,21
 117:2 120:5,10
 121:18 133:22
letter 5:24 6:19,21
 7:4 82:10 99:20
 100:19 101:8,10
 101:13 182:15,17
 182:22 183:14,18
 184:1,21 186:1,2

186:8,9,16 193:5
 193:7,8 202:2,6,7
 202:8,10,17,19
 202:22 203:2
 204:12 230:25
 231:1 242:16
 248:15 268:6
 274:15
letterhead 196:2
letters 6:18,23
 71:1 77:18
 181:21,24 182:1
 182:9 184:9
 262:21
let's 14:6,18 16:13
 17:9 18:25 20:22
 23:6 24:2,20 27:3
 29:25 32:11
 34:19 35:22
 47:17 48:12 49:1
 49:6 54:14 58:22
 62:25 63:16 66:4
 66:19 67:13 68:3
 68:4 69:17 72:7
 72:17 73:21 74:9
 75:3 78:21 79:14
 80:20 81:21 88:7
 90:6 93:2 96:4
 99:5,6 106:16
 109:21 116:7
 128:9 157:14
 158:8 162:18
 199:19 201:11
 206:8 207:12
 216:14 224:11
 230:22 232:2
 236:19 241:7
 242:12,12 243:17
 248:7,18 253:4
 260:22 270:2,2,9
level 106:7 107:12
 108:5,10,11
 126:24 135:21
 147:5 149:15
 160:5 169:3
 185:13,13
LEX 1:15
lie 265:5
lies 187:9,9
life 122:15 131:7

171:12,19 172:19
lifespans 57:22
Lifetime 129:5
life-time 129:12
light 269:3
limit 114:11
limitation 156:11
limitations 140:2
 140:17 185:9,10
 195:12
limited 49:4
 114:13 139:18
 189:10
limits 234:21,23
line 7:3 85:7,7
 114:1
lines 238:5
lining 205:10
Lipschitz 74:15
 82:3
Liptschiz 72:25
list 259:12
listed 137:20 149:8
 259:10
listen 61:23 263:22
 263:24
listened 268:1
listening 61:12
lists 241:12,12
literature 6:11,12
 6:13,14,15,16
 28:19 29:12,21
 58:2 60:1 115:23
 116:3 118:10
 134:24,25 136:21
 141:5 239:6
lithium 41:9
litigation 18:11
 228:15
little 23:19 54:10
 86:13 96:16
 98:19,20 143:14
 163:22 169:12
 192:20 244:7
 262:6 274:13
lives 121:22
load 87:9
located 8:8 30:14
 183:20
location 19:25

long 147:15 243:10
 256:24 266:24
 267:19
longer 82:17
 108:24 132:1,17
 213:21 257:4
longitudinal
 113:15
look 9:24 10:3,9
 14:18 16:12
 18:25 26:25 43:9
 43:21 46:25
 53:15 56:12
 57:24 62:10 66:4
 74:9 77:14 78:21
 88:7,16 90:6
 91:12 99:5,7
 100:1 106:16
 116:7 119:17
 128:9 130:20
 133:14,15 136:1
 142:10 146:19
 152:2 153:14
 155:8 165:4
 166:6,16,19,21
 167:3,22,24
 168:2,5,14,17,18
 169:20 170:24
 173:12 175:12
 176:10,12 183:23
 187:2 193:13
 194:25 205:5,8
 206:13 209:3,17
 210:16 214:9
 217:20 225:25
 230:22 232:2
 241:7 242:12
 251:8 260:22
looked 44:16 70:3
 78:6 89:22 91:9
 126:3 127:23
 135:10 145:22
 148:18 165:3
 187:12 189:1
 204:22 205:1
 213:17 246:6
 250:13 258:25
looking 13:15
 70:14,15 73:19
 125:13 128:1

132:14 151:3
 172:18,19 189:22
 199:19 205:11
 209:5 210:4,9,20
 210:24 211:18
 213:15 214:6
 217:3
looks 51:20 52:16
 88:20 104:2
 105:25 153:1
 156:16 175:19
 232:6 251:9
Los 3:5
loss 34:13
lost 30:1 274:18
lot 146:16 165:15
 167:19,20 172:16
 172:20 177:4
 270:12
low 29:7 116:14,21
 120:5,9 121:17
lower 152:23
lunch 109:14,17,18
Luncheon 109:24

M

m 5:8,10,11,15 6:2
 6:21,21 45:22
MacNell 243:23
Magazine 77:21
 83:16 214:19
magnitude 158:5
main 54:13 177:1
maintain 273:13
major 12:18 14:9
 61:4 76:11
 112:24 113:8,19
 120:7,18 121:7
 131:14,20,21
 132:5 134:8,15
 135:15,22 136:9
 140:17 143:8
 145:2 147:13
 151:5 165:2,6
 203:6 220:8
 227:10 253:23
 257:1,4
majority 12:1
 41:19 42:10,23
 128:21 179:5

223:9,12,21,22 224:8 256:15,17	212:6,8 216:6 217:7,13 218:9 219:15,16 222:12 223:2 225:11 226:9,11 229:14 230:22 232:2,16 242:10 260:2	245:9 mean 28:7 29:14 76:1 78:23 79:21 87:19 102:11,18 108:9,10 121:18 133:11 143:18 145:13 152:5,16 152:21 155:16 156:19 157:7,7 159:7,8,10,12,12 168:21 169:25 180:18 217:13 223:17 233:10 235:18 245:22 246:7 252:5,7,9 255:12 256:9 267:11	197:11 243:6,8 244:8 247:4 255:16 measuring 163:25 med 118:5 138:12 medical 4:19 28:19 30:12,13 138:1,4 161:10 179:5 193:16,24 194:5 254:21 262:25 medication 108:23 118:24 140:25 144:4,6 150:2 173:22 174:6 188:7 189:16 190:2,17 193:1 204:5 211:10 219:5,11 222:19 255:9,15 256:1 256:11	5:22 6:4 90:17 231:3,6,7,8 memory 83:25 85:1 106:12 178:14 198:11 222:11 226:1 Mental 5:1 36:5 178:23,25 179:2 179:7,13 mention 236:5 mentioned 121:16 121:17 212:9 213:20 214:17 merits 196:15 Merrill 100:23 message 32:4,8,10 met 92:6 110:20,23 144:18 159:3,4 methodology 71:6 Michael 174:11 Michele 2:17 275:2 middle 87:24 Mike 59:18 74:12 75:7 76:10 231:15,16 Milan 220:16,18 mild 108:21 152:10 256:16 257:6,8,11,12,16 mildly 257:24 Milen 220:14 million 95:14,22 mind 94:23,24 127:5 minimal 108:15,24 minus 102:8 Minnesota 2:1 8:22 minute 30:1 54:12 71:8 102:24 215:15 225:18 264:11 272:16 273:5 minutes 40:3 43:13 43:14 66:18 201:10 262:12 265:19 267:20,21 268:8,10 269:5,6 269:8,11,12 270:17
maker 101:20 making 142:8 148:5 149:18 169:11 175:3,5 274:3 male/female 127:18 management 74:15,17 255:9 256:4,8,9,11 Manhattan 30:15 manner 176:6 manual 83:3 manuscript 65:19 67:6,15 69:9,19 69:21 75:5,5 83:14 94:9 185:8 193:17 197:22 231:13 man's 180:19 map 19:25 maps 16:16 March 4:20 30:12 215:1 218:1 mark 10:8 32:12 68:4 88:8 marked 11:15,16 14:17 17:19,21 18:9 19:2 20:13 23:12,13 30:5 32:14 34:21 35:24 51:13,15 62:8 63:14,16 68:6,23 72:8 80:11,14,17 81:3 88:10 90:9,11 91:25 99:9,22,24 100:15 103:12,15 106:15 111:5,11 111:13 122:20,22 123:16 141:24 150:13 152:25 153:7 155:6 174:9 177:23,24 182:5,8,19,21 183:24 193:11,13 195:20,21 201:21 201:24 205:22	market 233:18 235:11 236:17 marketing 234:21 237:6,12 240:9 marking 81:5 155:2 260:3 Marsh 139:16 Martin 8:5 16:6,24 21:18,20 24:13 65:18 74:12 75:6 150:15,18 230:15 231:10 242:17 Marty 75:13 232:19 Marty's 18:6 massively 141:9 match 169:23 materially 106:4,5 mathematical 191:19 mathematically 152:4 191:18 matter 19:8 80:21 125:18 129:23 180:17 187:12 260:17 maturity 140:12 ma'am 63:12 263:13 McCafferty 4:14 7:4 18:1,4 54:15 55:1 82:2 174:22 182:25 198:16,17 231:16 266:7 MD 262:4 MDD 13:12 20:21 21:12 25:9 32:1,6 34:16 35:18 40:24 62:22 65:24 67:8,17 69:9 92:9,10,15 112:25 116:11 131:16 205:19	meaning 26:18,22 231:15 meaningful 70:7 144:6,16 meanings 251:4 means 142:22 152:2 160:3 255:14 meant 36:23 42:3 58:10 85:17 200:2 217:15 measure 21:11 31:24 57:23 156:25 176:13,18 244:4,17,20 245:13 248:6 measurement 244:25 measures 14:1,5 20:8,18 21:8 25:5 25:8 31:21 44:17 58:5,7,9,19 70:5 70:8 148:22 153:25 154:18 155:20 156:3 160:8 163:23 164:4 168:6,10 168:15 171:3,6 171:10,12,19 185:2,5,12 187:1 187:5,20 188:10 189:3 190:16,19 190:20,25 191:2	medicines 125:13 138:16 139:2 140:15,15 181:4,11 233:18 245:8 medicine 168:4 184:3 192:16 meet 143:22 144:4 159:17 169:22,24 257:4 meeting 5:6 64:9 64:11 91:8 93:10 93:14,25 101:4 101:11 121:2 145:19 192:14 198:3,7,25 199:3 218:3,7 225:5,24 228:13 meetings 148:15 238:16 239:5 melancholic 134:4 member 33:19 34:8,11,11 93:22 93:22 146:7 members 22:10 40:20 memo 107:2,5,6 142:1 209:21 210:10 memorandum	

23:17
notes 74:22 149:10
 214:24 275:12
Notice 130:14
noticed 16:4
 114:12
notify 274:4
notwithstanding
 144:17
November 56:18
 63:8 104:13,22
 121:1 183:12
 198:3,25 199:3
 242:19
number 8:14,19,24
 19:23 27:16,16
 39:16 41:8 47:12
 49:22 50:2 57:9
 60:6 63:17 64:20
 67:1 69:1 70:7,11
 72:18 83:9 89:20
 97:21 104:23
 105:10,15 128:9
 129:16,18 131:13
 135:6 137:1,3,3
 167:8 179:9,11
 183:3 191:10,25
 192:3 198:13
 201:15 207:12
 210:5 222:6
 229:12 231:13
 240:25 248:14
numbered 99:19
 100:10
numbers 69:3
 103:7 131:2
 200:25
ny 89:7
N-A-M-I 39:19
N.Ryan 5:17 7:7
N.Ryan/M 5:15

O

Oakes 55:2 174:23
oath 9:21 275:5
object 16:8 17:1,2
 21:19 22:19
 26:15 27:21
 28:21 29:19
 37:17 38:16 39:3

39:10 41:1,21
 43:1 44:2 45:11
 45:22 46:21
 47:14,22 49:24
 50:5 54:1,24 55:4
 55:24 56:25 57:5
 60:20 61:8,15
 64:23 65:21,22
 67:10,22 69:10
 77:5 80:5 84:4
 87:17 89:24 93:1
 94:12 95:6,15
 96:11 97:3 98:2,3
 106:9 114:1
 115:21 123:25
 126:13 186:3
 194:17 197:5
 215:8,23 235:1
 241:25 248:9,23
 249:4 250:25
 252:13 254:6
 258:5 263:3
 269:14
objection 45:4
 46:3 50:13 61:18
 62:1 67:13 75:20
 77:6 79:11 114:5
 115:1 116:23
 118:1 121:12
 123:25 125:15
 132:9 135:3,24
 136:8 137:16
 139:11 140:5
 141:1 142:25
 143:9 144:8
 145:4 148:2,20
 155:22 156:5
 158:1 161:5
 162:11 163:11
 166:23 172:4
 174:17 180:4,10
 181:7,15 184:17
 191:9,12 211:21
 213:10 215:14
 216:25 218:5,24
 223:16 234:4
 235:22 239:15,24
 249:25 250:9
 251:14 270:4
 271:16 272:7

objections 114:4,7
 141:20 275:7
objects 269:7
obligation 43:5,7
 43:12 76:3 97:13
 168:7
observation 52:18
 52:22 53:4 55:20
observed 52:16
 259:2
obsessive 225:2
obtained 116:19
obviously 13:4
 22:12,16 26:11
 40:18 41:22
 58:18 90:14
 91:10 122:13
occur 108:19
occurred 64:21
 83:7,22 105:11
 108:20 208:13
 218:19 219:11
occurring 120:19
 120:21,24 201:5
 211:9
occurs 114:6
OCD 225:7,10
October 1:22 2:17
 4:18 8:1,4 18:2
office 3:12 18:14
 21:23 232:18
 242:20 243:14
offspring 122:4
Oh 33:8 38:11 63:9
 80:19 106:22
 139:3 210:3
 224:6 242:8
okay 9:23 10:8,16
 11:6 12:4,17,25
 13:15 14:6,18
 15:4,15,18,24
 16:23 17:9,10,21
 17:23 18:8,18,25
 19:18 20:3,5,10
 20:16,19,22
 21:16 22:4,12
 23:1,13 24:2,8,18
 24:20,24,25 25:2
 25:10,19 26:2,5,8
 27:3,14,19,25

28:12,18 29:3,13
 29:16,25 30:7,13
 30:16,20,23,25
 31:7,15 32:3,11
 32:15,20 33:21
 33:24 34:14,19
 34:24 35:5,16,22
 36:2,9,12,14 37:6
 38:11,14 39:13
 39:24 40:6,10,14
 40:21 42:5 43:17
 43:23 44:7,12
 46:8,13,24 47:4,9
 50:9 51:6,14 53:8
 53:9 55:12 56:9
 56:17 57:3 58:17
 58:21 60:25 61:5
 61:21 62:12,21
 62:25 63:16,23
 64:2,8,12 65:9
 66:4,19 67:19
 68:16 71:8 72:12
 72:20 73:21 74:6
 74:9,18,21,23
 75:1,3 76:8 77:10
 77:12 78:3 80:13
 81:7,8,16,22
 83:16 84:1,15,23
 85:23 86:3,6,10
 86:14,21 87:7
 88:12,19 89:11
 89:15 90:24
 91:12,22 92:12
 94:7,21 96:22
 97:1 99:5 100:5
 100:14,17 101:3
 101:12 102:6,11
 102:14 103:8,12
 103:20 104:2,4
 104:14,16,23
 105:9,17 106:16
 106:25 107:24
 108:2,4,9,19,25
 109:7,21 110:12
 115:13 119:4
 120:16 123:6
 124:5 133:4
 139:4 144:14
 153:11,12 154:9
 155:2,4 158:8,22

159:20 162:1,5
 178:5 180:7
 182:7,20 183:13
 187:14 189:14
 190:25 193:5,12
 194:2,14 195:8
 197:3 199:19
 200:9,17 201:3
 207:12 208:10
 209:21 214:8
 215:2 217:6,18
 218:18 222:12
 223:1,8,21,22
 224:6,19 225:11
 227:2 228:8
 229:1,8 230:5,8
 230:19 232:11,15
 233:4,11 241:7
 241:12,21 242:12
 242:21 243:17,21
 244:11,18,23
 245:5,9,14,17,20
 246:19,23 247:2
 247:7,11 248:7
 248:13 249:9,18
 250:5 251:11
 253:4,10,19
 254:14,18 255:4
 255:12 257:6,10
 257:18 258:10,14
 260:22 261:4,8
 261:14 262:5,9
 262:20 266:10
 274:6,14
once 22:1 84:14
 116:15 176:25
 254:10 269:10
ones 24:2 43:24
 61:1 65:2 105:16
 127:12 135:5
 137:25 159:4
 164:8 170:4
 172:24
one's 75:7
onset 113:7 130:21
 131:4
on-drug 209:5,5
 209:16 210:20,20
 211:19,19
on-therapy 70:18

- 206:18 207:6
211:1,2,3,5 212:1
212:3
open 79:25 140:13
opened 210:16
opinion 42:2 44:25
58:14,23 59:17
59:23,25 74:16
138:15,18 143:5
143:10 260:16
270:10
opportunity 269:8
269:9 272:15
273:7
oppose 264:2
opposed 140:24
Orange 1:1 8:14
270:5
order 23:6 30:2
51:21 73:23
74:11 130:14
244:12 261:1
267:2 273:22
ordinary 152:13
organization 33:13
34:5 36:6,7 99:20
234:5 237:9
organizations
40:19 237:16
origin 100:10
original 71:1 87:21
119:18 125:22
202:1 215:19
253:4 273:4,14
273:15 274:17
originally 16:15
78:15 254:22
Origins 91:17
or/and 234:24
ought 237:11
outcome 14:4
20:18 21:10 25:7
31:24 44:16
58:13,19 70:5
153:24 156:3,25
168:6,10,15
185:2,5,12 187:1
187:5,20 188:10
189:3 248:6
outcomes 41:11
154:18 155:20
163:23 167:23
outline 156:14
outlined 157:10
267:1 271:2,6
outpatients 20:21
21:12 25:9 32:2,7
34:17 35:19
62:23
outside 229:9
262:24
overall 41:13
125:25 131:7
152:5 188:12
213:4
overdose 116:14
116:22 117:2,16
117:18,19,20
118:19,20,25
119:3 120:5
121:18,19
overdoses 117:6,8
overly 258:17
overstatement
194:11
overwhelming
122:11
O1 6:19
-
- P**
-
- P** 3:1,1 5:20 70:13
73:17 75:17
76:19,25 77:3,25
78:5,7,9,11 84:16
127:3 159:5,14
159:20 160:3
169:1,3,16
185:13,16 186:21
188:18 244:19
246:4
Pace 143:24
page 4:3,6 6:7
19:22,23 24:23
51:18 52:5,7
87:23,25 90:19
90:23,23 91:13
91:25 112:21
116:7 121:23
124:21 134:14
142:5 154:12
170:22 183:23
196:6 199:20
200:22 206:13
207:13 210:16,18
212:20,23 217:20
220:1,2 222:13
227:2,3 247:19
260:5 261:9,15
pages 10:13 19:4
51:24 209:17
265:14
paid 95:4,21 96:9
96:13,23 97:24
98:15,25 99:3
101:20,25 102:8
102:25 103:5
Pam 9:7 19:7
267:3
Pamela 1:11 3:13
8:19
paper 43:10 46:10
46:20 47:7,24,25
48:5 49:23 50:3
50:18,21 53:11
53:13,21,22,24
54:7,9,11 55:22
56:12,19,24 57:6
57:15 59:16 60:8
60:9,14 70:2
71:24 73:2,18,19
75:15,23 76:13
77:16,23 85:18
85:20,24 86:1,4
89:11 93:4 98:17
98:22,24 118:8
157:13 171:24
175:20 196:17,18
200:17 205:24
207:7 214:14
216:8,20 222:16
252:19 253:11
256:10
papers 74:17 116:6
117:5 213:22
PAR 6:20
paragraph 85:4
142:7,11,12
151:4 171:11
184:21 187:15
190:15 195:2
196:9,24 197:4
199:25 200:1
203:25 204:1
216:12 227:4
243:1 260:5
261:17
paralleled 105:23
parameters 227:19
248:4
parcel 78:22
parenthesis 248:1
parents 122:4
204:4
paroxetine 12:15
12:23 13:10,11
13:18,21,24 14:1
20:7,20 21:7,11
25:4,8,19 31:20
31:25 32:6 34:15
67:8,17 83:8,10
91:20,22 92:3
152:3 155:18
156:17 159:3,7,9
159:12,13 168:25
169:2 171:4
177:17 179:21
180:1,15 185:3
185:17 186:23
195:7 197:16
203:5,9 204:10
206:2 218:20
220:14 226:18
227:9,12 248:3
paroxetine-treat...
203:14
Parsons 202:7,17
203:3,7 204:12
part 51:23 78:22
82:13 91:25
93:17 94:2,5 97:8
112:8,23 151:3
189:5,23 192:16
213:8 221:10
225:20 236:3
274:16
partial 75:14
194:19
participate 93:13
101:4,11,14,19
148:15 267:7
participated 103:4
participating
101:18 105:11
225:14,23
participation
260:14,18
particular 29:8
41:3,5 44:16 91:7
91:10 119:21
142:20,22 188:7
189:16 190:2
203:7
particularly
230:12 250:6
271:20
parties 268:18
269:9 275:14
parts 112:9 128:7
189:6 192:12
252:20
Party 273:10
pass 82:13 144:25
passed 43:18 47:10
47:10
paste 174:25
patient 28:12 89:5
89:5 117:25
118:24 119:15
150:3,4 151:1
204:9 259:2
patients 33:17,21
33:23 36:8 79:1,3
92:9 103:9 106:2
114:23 115:18
127:11 132:4
138:7 140:3,3
141:11 143:7
144:7,16,22
145:2 149:18
150:1,10 151:21
152:18 174:3
176:23 191:22
199:12 201:5
203:14 204:8
206:11 207:9
208:11 218:4
222:9 233:15
235:21 237:13,20
239:14,23 259:16
260:14

- pattern** 185:16
186:21 188:17
patterns 175:13
pause 11:7 17:15
66:24
Paxil 10:1,6 11:3
14:8 22:17 26:2,5
29:17,23 35:18
40:23 41:18 42:8
42:22 46:15,25
47:5,10 50:4
52:14 53:2 60:13
61:3 62:22 64:16
71:13 75:18 82:9
85:11,15 87:1,9
87:15,16 89:4,6
89:12,16,17,19
89:20 91:22
92:11 97:25
101:20,21,24
117:14 143:6,7
143:19 144:15,21
146:22,25 147:12
150:4 157:23,24
158:20,23 159:16
159:24 160:10
162:19,24 164:21
165:11,22 168:23
169:7 170:1
171:1 172:2
173:8 175:17,24
176:22 179:21
189:20 199:12
207:9 208:25
213:7 216:16
231:11 233:9,9
233:10,10,10,14
235:8,11,20
236:11,17,24
237:6,12,19,24
239:13,14 240:9
240:10 242:18
245:18 247:7
250:7 253:22
254:11 258:4,8
258:11,23 262:18
Paxil's 238:6
pay 34:8 97:13
paying 22:16
Peabody 151:15
- PEACHTREE** 3:9
pediatric 65:24
67:8,17 83:2,13
91:7,18 92:9
114:21,23 115:18
117:25 118:23
140:3 143:7
145:2 170:2
174:3,6 175:25
176:23 191:22
192:2,4 193:2
207:18 208:10,14
212:11 213:7
215:4,4,13,21
218:3,4 220:8
222:8 225:2,4,16
225:23 233:15
235:12,21 236:12
236:17,25 237:6
237:13,20,23,24
238:11 239:14,23
240:9,11
pediatrics 216:24
peers 204:5
peer-reviewed
220:21 221:14
penalty 275:17
Pennsylvania 1:7
1:10,18,22 2:8,16
3:14 8:1,7,9,18
275:18
people 22:13,16,20
22:24 29:17,22
31:5 33:22 35:11
37:14 42:16 45:1
45:2,9,19 66:7
78:10 82:7 101:2
122:13 141:6
159:3 165:14
170:21 172:18
198:10,13 234:13
255:14,15,23
256:1,18 271:19
percent 86:25
122:17 128:3,22
129:6,19 154:2
154:20 157:1
159:1,2,4 247:5
257:5,22
percentages
- 157:20 201:1
Perera 5:21 72:25
82:3 88:15
Pereva/E 5:20
perfectly 217:18
248:19 251:3
perform 164:22
245:9
performed 157:23
157:24 158:20,23
160:10 162:19,24
212:11 262:3
period 70:18,19
126:4 173:14
209:5,6 210:21
210:24 211:13
257:23 268:25
perjury 275:17
permit 188:17,23
persistence 135:8
persistent 131:19
person 157:16
225:14,23
Personal 1:12
personality 134:19
personally 18:22
29:4,10 60:7
persuade 221:25
Pfizer 4:8 12:3
pg 5:25 7:3
pharmaceutical
12:2 233:17
234:2,16
pharmacology
138:25 184:7
phase 107:16,17
222:16 231:13
Phil 88:15
Philadelphia
265:22
Philip 81:25 82:2
philosophy 184:4
phone 82:21
147:16 225:15,23
phonetic 163:20
physically 171:2
physician 118:21
220:22 271:25
physicians 22:6
30:17,21 39:9
- 40:7 61:5 116:18
119:7 121:6
146:22 180:24
183:13 221:15,17
237:16 238:16
239:4,6
Ph.D 52:15 184:2,6
PI 179:9 261:22
pick 72:18,18
172:25 187:20
194:17
picked 190:24
191:2
picture 131:9
133:5,9,16
151:15
pieces 76:11
pile 14:24 210:12
214:11
pill 157:23,25
162:20,24 164:23
171:2 199:13
pinpoint 226:5
PIs 198:11
pissed 265:23
Pittsburgh 1:22
2:15 3:12,14 8:1
8:6,9 104:10
107:4 148:25
198:12
PI-04-012879 2:7
8:24
place 79:8 261:25
275:4
placebo 13:25 14:1
14:4 20:7,17 21:8
21:10 25:5,7
31:20,24 87:2
89:5,13 92:3
145:25 150:4
152:4 155:18
156:17,18 157:23
159:4,13 162:25
164:2 168:25
171:5,16 173:8
173:10,18 185:18
186:23 187:19
191:3,5,15,17,23
192:1,6 199:13
207:10 208:25
- 218:12,19,22
219:9 220:10,13
222:3 227:12
248:3 255:14,24
256:3,6,7
placebos 146:2
placebo-controll...
227:8
Placebo-treated
171:9
placed 118:22
places 194:4
234:23 271:8
Plaintiff 1:4 261:1
269:1,5,6
Plaintiffs 1:16 2:6
2:14 3:3 4:6 8:15
8:20,25 9:5 51:19
74:11 90:16
99:18 110:11
151:17,20 166:13
166:15,18 174:10
194:9 205:23
209:25 213:20
214:17 216:7
217:8 218:10
222:5,9,13
223:10,13 225:12
228:14 235:15
Plaintiff's 100:5
150:14
plan 160:1 219:22
planned 170:4
251:2
plans 131:25
please 9:2,13 11:23
15:5 17:25 18:7
19:20 20:16,19
21:6 24:21 25:3
31:18 34:25 36:3
48:15 49:19
54:20 59:2 61:21
62:10 67:3 72:20
73:1 75:11 76:8
81:23 83:14
87:10 88:16
89:10 91:16
106:13 107:16
110:3 111:8
116:9 125:1

128:10,15 129:4	264:2 266:6	prescriptions	208:8	259:3 272:12
133:19 142:13	positive 180:18	116:17 119:7,12	prevalence 129:5	problem 84:11
150:25 154:14	238:6 243:6,8,12	120:2 126:10	prevent 140:2,17	problematic 150:7
155:14 158:16	244:1,2	127:9	162:13 221:21	211:4,7
189:24 195:9	possibility 27:13	present 9:10 10:22	Prevention 122:2	problems 163:13
201:19 203:2,13	possible 156:2,7,10	12:7 43:6,10	preventive 113:3	200:10 203:18
203:20,24 212:25	206:10 215:12	45:24 46:2 62:5	preview 119:19	Procedure 273:2
214:12 219:18	216:14,23 218:21	64:9 66:7 91:17	previously 9:15	procedures 149:18
220:5 240:23	259:3	94:16 124:17	16:6 90:8 141:23	proceed 9:13 49:19
248:1 251:17	possibly 37:11	198:8,10,19	pre-adolescents	67:3 110:3
260:8 261:20	92:5 160:4	221:25 236:23	135:14	147:21 158:16
268:17	post 206:19 252:24	237:4,23 239:7	primarily 10:4,24	201:19 240:23
pleased 94:2	252:25 253:1,9	239:12,22 240:8	11:10 30:22	268:17
plus 87:15 89:19	253:12,14	presentation 4:8	117:8	proceeded 268:22
147:15 164:7	poster 4:16 18:6	4:11,17,19,21,23	primary 26:9	proceeding 200:22
170:4 206:18	220:17	5:1,4,5 10:18,19	41:19 42:10	proceedings 17:15
209:5 210:20	posters 234:24	11:19,24 12:14	54:13 56:3 57:23	66:24 275:3
211:2,5,12,19	post-treatment	13:1 14:7 15:2	70:5 142:21	process 84:19
212:3 257:5	70:19 159:8	18:6 20:13 21:17	143:22 144:5,17	145:9 161:2,9,17
pneumonia 137:14	potential 83:2	22:2 23:18,22	153:19,21 154:10	203:8
pocket 97:2	234:10	24:14 31:1,8	154:16,17 156:25	produced 18:10,14
point 12:13 13:6	potentially 83:5,9	32:17 33:24	158:20,23 159:17	51:20 232:18
13:22,23,25 14:3	power 12:12 18:2	34:15 35:1,17	159:22 160:16,19	242:20 265:13
18:3 31:20,23,25	265:6,7	36:4 39:18 40:15	162:10 163:23	producing 177:5
36:16,25 37:5,18	precise 113:2	40:22 41:2 61:2	167:23 168:6,9	product 234:3
38:3,5 71:23,25	131:2	61:13,24 64:15	168:15 169:21	productive 49:3
78:14 87:7	precisely 174:13	66:7,12 123:10	176:3,9,13,18	professional 2:14
101:16 106:8	preclude 93:10	123:17 124:1	185:2,5 187:1,5	11:12 33:13 42:2
108:16 128:10	predated 223:10	220:17	188:9 189:3,18	233:21 237:9,16
131:23 142:7	223:14	presentations 10:1	189:22 190:4,19	professor 97:12
148:11 159:10	predefined 42:24	10:3,4,17,18	247:3 248:6	professors 30:23
165:15,17 209:17	250:8,11,12,23	11:13 16:25 32:5	271:6,9,14 272:3	profile 116:14
245:20 246:1	253:16	63:25 223:1,3,4	272:5	171:21,22 173:20
249:16 257:2	pregnancy 136:15	223:20 234:24	prime 122:6,7,8	173:21
pointing 47:23	preparation 12:6	235:17 238:14,17	principal 226:20	program 92:11
125:22	202:22	presented 11:9,10	principle 146:8	234:11
points 13:21 21:15	prepare 63:19	11:13 12:21,24	148:14 149:9	progress 6:1 104:3
73:1 107:23	100:12	16:14 25:17	179:10 180:22	104:8 107:13
poisoning 137:15	prepared 12:5	41:25 54:8 64:3,5	181:1 207:4	Project 100:25
population 119:15	16:2,15 19:16	87:23 123:23	printout 72:22	projected 22:13
193:2 236:12,17	21:18,20 24:6	124:15 178:18	prior 44:13 82:5	promote 233:18
236:25 237:6	31:13 32:22	197:16 228:12	89:7 102:3 112:7	235:11,20 236:17
240:10,11	56:11 66:13	234:25 236:10,14	138:21 172:6,23	promoting 234:3
populations	81:19 89:1	237:15 238:19	187:19 268:18	237:5,12 239:13
116:18 119:7	100:11 104:16	239:3	priority 251:4,6,9	240:9
portion 20:23 31:7	124:10 182:23	presenting 139:22	252:3 253:1	promotion 234:21
121:24	238:16,18	238:6	probably 73:24	prompt 113:2
portions 112:20	prescribe 61:6	preserve 273:4	86:19 97:21	254:9
122:24	prescription	presumably	149:9 169:18	prompts 124:18
position 82:14	120:17 125:13	119:22 147:17	174:25 202:1	proof 126:24

142:15,16
proper 252:11
 253:10
properly 80:3,9
 147:12 178:7
proponents 139:14
proposal 147:19
proposed 52:12,25
 67:16 175:15,22
proposing 55:25
 56:3 67:7
propounded 275:7
protective 51:21
 261:1
protocol 154:17
 247:3 259:12
prove 127:4 181:4
proven 126:14
 139:8 181:11
provide 127:6,8,13
 144:6,15,21
 145:1 167:17
 177:15 180:14
provided 63:24
 123:11,17 158:4
 179:24 211:1,14
provides 143:14
proxy 151:16
Prozac 167:16
psychiatric 5:6
 33:15 36:7,7 60:1
 64:6 114:24
 115:19 117:22
 180:25 203:16,21
 233:23
psychiatrist
 117:21 149:4,5
psychiatrists 11:11
 11:12,25 140:22
psychiatry 4:12
 15:8 30:22 31:4
 33:14 58:2 112:6
 112:19 124:11
 161:12,21 162:3
 162:7 182:11
 183:16 195:25
 196:14 197:13
 202:5 219:21
 233:24 244:17
psychological

184:3
psychologists
 11:11 22:8 30:21
psychomotor
 51:11 134:6
 175:10
Psychoneuropha...
 33:12 62:16
psychopathology
 135:18
psychopharmac...
 7:1 33:14 226:14
 226:16
psychophysiology
 11:1
psychosocial 44:16
 44:18 125:5
 134:11 172:14
 204:3
psychotherapies
 140:19
psychotherapy
 138:20 140:4,14
 140:16,24
psychotic 257:15
Psyconeurophar...
 4:22 34:1
public 1:3 2:5
 101:1
publication 69:19
 185:22,24 235:18
 254:23
publications 121:8
publicly 98:15
publish 65:19 67:7
 67:16
published 56:20
 67:21 69:22
 70:25 71:3 76:5
 85:18 112:6,15
 112:17 113:5
 115:3,9,23 117:5
 146:14 160:25
 161:4,23 162:8
 162:14 163:15,21
 167:8,13,14
 170:19 179:16
 181:24 184:23,24
 185:22 186:10,11
 186:12,13 187:13

199:16,22 202:5
 209:3,10,13
 217:9,10,12,15
 217:18 218:11
 219:20 220:20,24
 221:2,13 226:14
 226:24 228:12
 236:16 239:6
 271:4
publishing 69:9
Puck 6:25 219:22
pull 47:3 258:2
punitive 270:7
purporting 99:13
purpose 10:17,20
 10:21,22 27:9,10
 59:14 101:7
 231:22 237:5,12
 237:19 239:22
 240:8
purposes 15:9
 236:24 239:13
push 120:14
pushed 192:18
put 42:19 53:10,12
 53:21,24 64:12
 66:14 73:22 91:6
 111:19 138:4
 147:11 166:4
 175:20 223:3
 238:20 243:11
 249:13 264:1
 266:5 273:23
 275:5
putting 214:5
p.m 110:3 158:11
 158:14 201:14,19
 240:18,23 268:14
 268:17 274:23,24

Q

qualified 140:21
quality 161:22
 171:11,19
question 17:4 19:3
 19:7 21:20 29:9
 29:15 35:8 36:18
 37:3,7,19,23 42:5
 42:7 44:8,11 45:7
 45:15,18,24,25

46:2 47:19 48:5
 48:25 49:7 52:24
 53:3,6,23 54:12
 55:11 56:2,15
 57:11 61:21
 67:11 69:8 76:16
 85:14 88:3,4 89:9
 89:10 94:21
 98:12 103:19
 106:12 108:4,7
 110:16,17 114:8
 119:4 124:19
 127:5,24 128:8
 130:18 138:21
 139:3,4,6 140:11
 140:13 143:1
 145:6 148:3
 158:2 164:6,17
 165:5,13 166:24
 168:5 169:19
 172:2 173:4
 175:23 184:22
 185:14 186:4,20
 187:4,15 189:24
 194:22 212:17
 214:8 215:24
 216:2 219:8
 235:25 239:25
 248:18,19 250:2
 251:1,20 253:5
 258:16 260:8
 266:16
questioned 222:5
 269:4
questioning 114:1
 130:16
questions 47:23
 82:16 83:15,17
 103:17 104:1
 110:9,14 123:1
 123:22 124:20
 133:5 141:15,18
 151:18,20 164:11
 168:7,20 175:8
 203:4 204:13,15
 229:21 233:10
 235:16 240:14
 262:20 263:11,13
 264:24 265:15,18
 265:21 266:7

267:6,16,17
 269:25 275:6
quick 49:6
quickly 82:11,20
 209:12
quite 125:10 185:4
 242:24 255:15
 271:10
quote 16:18 41:24
 160:4 246:18
 255:5

R

R 3:1
raised 106:8 108:5
 108:16
randomized 13:22
 187:17 197:10
 220:9
range 185:16
 186:22
rank 136:24
ranks 136:21
rare 176:8,12,15
rate 29:6 65:14
 120:17 125:9,10
 126:6,12 127:18
 136:14,17 191:3
 191:6,15,17,24
 192:6,11 218:21
 219:1 220:13
rates 125:7,14
 127:10,16,17
 134:19 192:1
 227:11
rating 151:7,11
 152:9 153:25
 187:25 188:3
 245:3 246:14
ratio 86:25 87:4
 89:4,12,15 213:3
 219:2,2
reach 26:8 41:18
 47:1,5 50:4 55:19
 60:13 84:2
 168:25 185:13
 187:6 190:13,19
 227:18 245:18
 247:8
reached 46:14

52:13 53:1	166:5 168:6,13	reclassification	redoing 16:21	176:17 203:22
126:24 169:16	234:13 243:16	78:12	reduction 154:3,20	204:9 207:9
181:22 268:19	reanalyses 70:9,12	reclassified 78:10	157:2 159:1	211:18 215:12
reaches 52:17,19	78:23	78:11 79:6 84:18	247:5	225:10 232:5
reaching 129:10	reanalysis 70:2,10	reclassifying 70:13	reference 189:14	251:23 259:2
read 20:6 21:5	reanalyzed 78:8	recognize 100:14	220:16,17 243:12	relationship 71:13
23:3 25:2 28:18	reason 8:12 18:16	111:14,23 193:14	243:14	75:18 259:16
28:22 29:12	18:17 74:6 88:23	195:23 230:15	referenced 77:8	relative 275:13
31:18 39:2 45:2	89:22 94:8,25	recollection 69:7	113:13	relatively 116:13
48:15,21,23	176:7 245:20,24	89:3 174:11	references 113:14	117:7 120:4,4
68:14 78:1,2 85:3	274:17	216:21 231:18	228:11	143:14 176:14
90:13,15 91:5,15	reasonable 53:16	record 10:9 11:18	referencing 107:4	191:5 217:11
91:24 112:22	122:11 190:24	11:22 15:4 17:3	referring 12:22	254:12
116:8 121:25	reasons 146:4	17:11,14,17,24	39:13 78:3,4 82:5	relevant 37:24
122:25 125:2	176:1 211:8	19:10 20:6 21:5	117:1 119:24	reliable 190:16
128:10 129:4	213:21 245:25,25	23:14 25:3 30:9	128:5 132:13	237:25
131:11,24 133:18	258:11	31:18 32:16	133:12 137:19	reliably 164:12
134:18 142:11,13	rebuttal 6:19,20	34:24 36:2 49:15	refers 227:14	188:4
154:6,14,24	272:16	49:18 59:12	reflect 83:24 94:23	relieve 273:12
177:13 178:1	recall 17:6 23:1	62:13 66:22 67:1	reflected 21:24	relieving 273:14
184:21 186:15	46:11 50:11,12	68:18,21,25 72:7	196:23 241:2	rely 61:13,24 62:4
187:14 193:22	54:17,22 55:1,10	72:21 77:13 85:4	refresh 69:7 89:3	relying 94:17
195:1,8 196:8,24	55:12 60:21 67:9	88:12 91:15,24	106:12 174:10	remains 185:15
197:3,6,7 200:14	67:19,23 68:1	100:17 103:25	216:21 231:18	186:20
203:1,12,19,24	73:15,19 74:23	104:6 106:18,25	refreshes 226:1	remake 23:25
212:25 219:17	74:24 78:16 99:6	109:22,25 113:25	refuse 168:14	remarkably 117:7
220:4,21 222:14	104:25 108:6	114:4,11 116:9	187:2 266:5	remember 29:7
227:24 228:6	137:2,6 145:16	122:25 130:1	Regan 82:2,5,24	31:2 34:6,7 46:8
242:24 243:1	145:17 146:7	142:13 158:10,14	regard 53:4 75:16	53:20 71:16 72:2
245:21 246:1	178:15 181:20	201:14 220:4	89:5,12 185:10	78:13 84:6 86:23
247:25 248:19	196:11 198:7	222:15 240:18,21	247:8 249:19	87:2,4,5,13 103:8
251:16,18 254:14	213:15,23 214:19	242:14 251:18	regarding 10:1	105:2,7 119:17
260:6,7,11	224:19 225:14,22	260:6,11 261:19	40:22 46:19	119:21,22 148:4
261:19	228:2,5 241:5	266:19,24 267:1	63:25 92:21	148:6,12 149:8
reader 158:4	249:24 254:18	268:14,17 272:11	262:22	183:22 193:23,25
246:20	255:4,9	272:14	regardless 121:4	194:3,6 197:2
readers 160:19	recalling 60:22	recorded 275:9	regional 40:18	198:14,15,18,21
162:9	78:18,19	record's 18:9	registraries 119:10	202:21 204:20,21
reading 75:25	receipt 18:7	50:16 269:13	119:11	204:25 224:23
77:13 173:5	receive 73:11,13	recovery 188:19	regulatory 91:19	225:3,9 226:3,7
228:2 248:5	received 18:19,21	recruitment	144:25 188:5	228:7 254:15
255:10 262:16	18:22 204:12	104:12	189:15,25 190:14	263:5
reads 142:7 157:16	214:18,20,23	recurred 113:16	rejected 74:17	remembering
157:21 190:15	232:14	113:18	254:25	225:25
197:4 271:11,25	receiving 74:23,24	recurrence 257:23	relapse 257:19	remind 27:12
realistic 139:20,23	193:23	recurrent 112:25	241:19	38:21
266:14	Recess 49:16 68:19	113:9 122:10	related 13:9 28:23	remission 14:2
realistically 97:21	109:24 158:12	128:11	79:6 91:7 92:5	20:9 21:9 25:6
really 54:11	201:16 240:19	Redacted 5:25	156:18,21 157:9	31:21
128:20 165:17	268:15	redefining 108:21	157:17 160:10	remissions 257:2

repeat 35:5 61:21 216:1	178:1	responded 77:19 83:18 84:1 202:18 262:21	199:17 220:18 221:5,10,15,18 221:18 222:7 223:5 224:20,25 225:15,16 226:25 228:17 237:9,17 238:15 239:12 247:23 259:24 271:1,5	revisions 230:20
rephrase 124:3 167:2	representations 122:24 266:8	responders 190:17	retardation 134:6	re-approval 107:10
replication 180:19 195:4,15	Representative 1:12	responding 229:20	retreat 35:2,7 147:15	re-open 269:18
reply 182:12,15,16 182:22 183:17 184:21,23,24 186:2,9,16 193:5 202:3,17,19,22 203:2 244:24 245:23 246:12	representatives 40:18 64:8	response 91:20 95:19 123:1 153:25 154:18 191:3,6,15,17,24 192:1,6 202:9 220:13 227:11 242:18,19 246:21 246:24 247:2 248:4,16 249:12 249:13,14,15 255:23,25	return 247:11	re-review 107:9
replying 183:14	represented 25:13	responses 77:17,24 181:25 248:20 263:1	Reuptake 121:20 126:11 138:15 203:11 220:7	rid 30:8
report 5:3 6:1,6 38:22,23 51:16 51:18 52:6 56:9 56:11,12,13,17 56:18 63:7,10 77:24 91:21 92:2 104:3,8 107:13 107:14 168:9 195:6 200:17 205:13,17 220:10 222:14,17,23,24 223:15 224:16 244:20 261:5,6,9	representing 9:7,9 24:15,19 92:7 98:4	responsibility 22:1	review 6:9,24 34:22 47:2 52:2 69:5 72:15 83:3 83:12 87:21 91:11 98:1,16,19 104:9 105:24,25 107:21 112:3,3 113:14 134:25 149:10 161:3,9 161:18,20 206:6 216:15 233:4 234:25 272:18 273:7,18	right 13:8,17 14:21 20:2,10 22:15 23:5 27:6 37:1,8 37:12 39:14 40:7 40:8 43:19 46:20 49:7 51:9 53:3 54:4,6 55:14,18 56:7 57:8,15 58:17 61:13,24 62:4 63:2,8,25 64:13,18 66:16 67:23 68:3 76:21 77:22 78:21 79:4 79:22 81:17 84:3 84:12,17 87:20 88:17 89:1,7 90:13 91:22 92:16,22 102:16 105:12 113:11 123:21 124:2,14 125:6 128:24,25 142:10 145:12,16 169:25 186:15 187:3,6 189:21 190:5,23 195:14 198:5 200:13 202:16 204:18 210:8 212:21 214:15 217:25 224:3 225:13 230:6,9 233:14 241:13 243:17 244:16 247:15 258:4 259:5 261:8 263:16 264:17 267:10 272:18 274:2
replying 183:14	request 36:5	responsiveness 114:8	reviewed 72:9 91:5 107:22 160:23 162:1 212:10	right-hand 170:25
reporting 183:14	requesting 101:3 101:10	responsive 172:25	reviewer 161:16 162:13 193:15 197:25 254:14 255:2	rising 137:5
report 5:3 6:1,6 38:22,23 51:16 51:18 52:6 56:9 56:11,12,13,17 56:18 63:7,10 77:24 91:21 92:2 104:3,8 107:13 107:14 168:9 195:6 200:17 205:13,17 220:10 222:14,17,23,24 223:15 224:16 244:20 261:5,6,9	requires 44:4 273:13	rest 107:25 109:9 168:2 197:1 204:1 234:9 244:16	reviewers 160:24 161:19 162:2,5 194:13 196:16 197:24 254:15,18	risk 86:25 87:4 89:4,11,15 92:3,8 106:7 107:12 108:5,10,11,15 118:15,19,20
reported 70:9 76:12 77:25 78:16 93:3 179:15 202:12 208:16 228:17	requirements 144:25 190:14	restless 28:5	reviewer's 193:22 194:15,18,25 195:23 197:20 212:24	
reporter 2:18 14:23 77:20 82:10 214:18 260:10 273:12 274:10 275:2	requiring 113:2	restlessness 28:4,8 28:10		
REPORTERS 1:23	research 15:13 29:14 100:20,23 112:7 117:22 134:23 179:5 185:11 205:18 219:23 231:12	result 219:11,24 255:8		
REPORTER'S 275:1	researcher 33:20	results 13:1,16 20:4 21:2 24:25 36:9,22 37:2,4 38:8 39:1 51:4 53:10 54:3 71:7 76:4 118:10 134:1 138:9,11 144:14,20,23 150:15,23 155:11 156:15 157:16,22 158:19 160:14,15 160:21 170:23 177:12 178:7,8 178:13 179:19 181:23 182:11 184:15 185:11,21 193:17 194:12,14 197:15,21 198:5		
reports 116:10 216:13	researchers 33:14 33:16,18 35:14 236:2			
represent 9:3,5 89:20 110:7 154:6,24 196:1	reserve 86:16,20 109:8			
representant 99:13	reserved 114:9			
representation 55:7 155:10	residents 30:19,22			
	resolve 256:16,18 256:23 257:12,14 257:15,16			
	respect 114:14 143:6 149:17 159:20 190:6 207:3,22 218:18 235:8 263:2 270:25			
	respiratory 137:13			
	respond 75:14 84:5 191:12			

- 122:3,14,15
132:6,24 199:10
207:8,24 208:24
213:3,9 216:14
258:19
risks 106:2,3,4
108:22 258:17
road 243:16
role 149:20,21
262:2
RONALD 1:14
room 117:19
Rosemary 55:2
174:22
rough 151:15
round 15:10 23:16
rounds 4:11 15:7
22:4 30:11,16
31:4 123:10,18
124:10
Royal 184:8
RR 213:3
rule 188:14 190:8
rules 211:11 234:1
234:6,15,19
235:7 273:2
run 36:8
running 48:17
Ryan 1:21 2:13 4:2
4:8,11,14,17,19
4:21,23 5:1,4,5
5:10,11,14,19,21
6:2,4 8:11 9:8,14
11:14,19 14:16
17:18 19:1 23:11
30:4 32:13 33:4
34:20 35:23
51:12 62:7 63:13
67:2 68:5,22
75:13 80:10 81:2
83:13 88:9 90:10
99:8,21 103:14
106:14 110:2,6
111:10,20 112:2
114:21,21 122:19
123:11 130:20
141:25 153:6
155:5,8 158:16
158:18 180:8
185:20 196:6
- 201:18,20,23
210:18 212:9
214:17 224:19
226:8 232:18
239:19 240:13,22
242:9 260:1
261:2,22 262:1
270:25 272:17,18
Ryan's 80:17
129:21 130:9
268:20 273:25
-
- S**
-
- S** 3:1
sad 172:19
SAE 83:3
SAEs 150:5
safe 146:3
safer 146:2
safety 67:8,17
120:14 154:11,15
157:12 171:23
177:16 179:14,25
180:15 216:15
225:16 237:4
238:11 239:3
salary 96:16 97:5,6
97:8,9,10
sales 236:11,24
237:19 239:14,23
240:10
Sally 228:15 229:1
262:24
sample 197:9
Saturday 243:15
saved 38:12
saw 22:17 25:11
39:4 102:1 199:9
saying 23:1 38:14
47:9 48:6 55:2
73:4 76:2 82:7
87:13 99:1 122:8
127:4 132:3
133:14 134:2
141:5,8 166:2,7
168:1,14 171:14
174:23 205:10
232:5 235:3
244:9,17 250:23
253:3
- says** 13:22,25 14:3
18:3 20:7 25:19
35:18 50:19
62:22 72:25
74:14 75:12
76:10,21 77:23
82:25 88:16 93:6
101:18 102:16,19
107:11,13 119:6
125:4 128:11
129:5 133:8,20
134:18,19 142:6
151:4 153:24
171:4 176:12
182:25 183:2
210:25 216:13,14
227:7,22 231:12
231:15 232:5,13
244:21 247:22
249:12 256:3
264:7 269:6
SBK 5:3
scale 151:7,14
154:1 164:24
187:25 245:2,3,6
245:10 246:14
scales 151:11
242:22
Scale-Revised
188:3
scheduled 188:20
schematic 131:1
scholar 15:11
scholarly 26:25
school 4:19 30:12
30:13 113:23
136:10
school-aged
135:14
science 100:25,25
143:12 180:19
187:9
scientific 10:23
11:13 15:12
106:1 116:3
180:22 234:24
235:12,17 236:15
236:23 238:15
239:5 252:3
253:15
- scientifically** 14:14
26:12,24 32:9
173:1 237:25
253:10
scientist 212:18
258:22
scientists 172:20
188:11
scope 114:2
score 151:6,13,14
151:21,24 152:1
152:7,9,17 154:1
154:4,21,22
156:23 157:5,7,8
159:6 163:1,6
165:21 166:10
247:6
scores 151:11
155:16 175:7,7
se 135:19
second 13:23 24:21
27:3 66:6 70:12
85:4 107:13
116:7 118:15
126:3 129:3
142:10 153:23
163:2 167:17
176:1,7,8 184:21
187:14 192:22
195:1,2,8 196:5,9
197:4 211:10
222:20 230:4
263:6 268:12
secondary 41:19
42:10 53:14,17
54:11 57:23 58:3
58:6 70:8 86:8
122:18 128:7
160:11,16,20
162:10,18,22
163:9 164:8
169:21 175:20
176:2,19,20,21
185:2,6,17
186:22 188:10,18
249:19 250:5
253:6 271:3
secondly 175:11
section 90:14,23
119:19 151:1
- 154:11,15 157:12
171:24 177:11,14
179:18 180:9
186:15 212:22
247:22
see 7:3 10:14 16:13
17:9 19:19,24
20:3,25 22:14
24:8 27:6 31:15
47:17 50:24 52:5
54:14 55:15
58:22 64:10 68:7
69:17 77:12
79:14 81:1 87:22
93:2 98:20,20,21
99:10 106:21
107:22 119:24
129:1 136:2
141:25 151:4
157:14,22 187:8
195:1 204:23
216:7,14 224:11
226:1 227:7,17
229:17 230:12,19
242:12 243:14
245:8 246:25
247:22 248:16
250:2 262:14
272:12
seeking 140:24
seen 22:21 25:15
65:15 71:10,20
71:25 90:7
100:15 101:10
135:21 137:18
182:1 217:11
226:2 235:2
259:24 261:2
selective 126:10
203:10 220:7
self 70:16,17,18,20
70:20 75:19 83:5
206:17
Self-Perception
171:22 173:21
send 272:20
273:15,16,25
274:9,15
sending 82:15
231:23

senior 33:14	severe 28:16	side 27:17,19,22	189:2,17 190:2	43:12,20 61:2,12
sensation 28:14	108:22 131:20	64:16 66:8,11	190:13 205:11	61:23 62:21
sense 54:11 164:13	150:6 256:22	104:12 116:13	single 13:17,20	64:24 124:20,24
229:3 251:20	257:13	120:5 170:25	143:11 163:2	125:3 128:16,24
sensitive 164:1	severely 257:19	signal 92:7,12,21	169:17 180:17	130:20,21,25
244:4,10,17,20	severity 152:17	93:3,7 213:2	214:6	131:1,8 134:14
245:7 246:3	shared 222:7	signature 272:21	sir 17:25 19:10	223:8,9,13
sent 83:17 100:16	sheet 107:12 274:9	273:18	29:17 32:16	253:21 254:1,4,8
107:5 174:12	short 109:12	signed 196:3	44:13 45:17 52:6	254:8
182:1,9 183:11	132:19	significance 26:9	55:11 58:16 60:5	slides 9:25 10:5
183:14 184:13	shorter 268:25	41:18 42:9,23	60:17 62:14	12:5,6,8,13 13:3
186:10 202:3	shorthand 13:4	46:14 47:1,6,10	88:13 89:21	13:7,9,19 16:5,10
232:20	275:12	50:4 52:13,17	91:16 104:6	16:15,24 17:8
sentence 122:1	shortly 82:16	53:1 55:19 60:14	107:1 110:20	19:13,16,17
142:10,12 153:23	show 11:16 17:21	84:3 159:17	112:10 138:22	21:14,25 22:12
177:14 190:15,22	18:8 19:22 23:13	169:1,22,24	155:15 204:2	23:23,23 24:1,1
195:2,9 203:12	24:13 26:22 27:2	170:3 185:14	222:22 242:14,24	27:15,16 41:16
203:19 231:14	50:15 51:14	187:7 190:20	247:12 255:10	66:13 123:22
247:25	54:19 55:5,15	227:19 245:18	256:15 260:4	124:1,9,15,18
sentences 85:6	68:13 77:13	247:8 250:7	site 39:5 91:6	222:6 223:4,6,20
203:1	78:18 80:13,15	significant 26:23	99:25 100:2	226:1 238:19
separate 33:2	81:5 99:24	65:3,4,16 66:8,10	125:21 198:11,12	239:1,2 253:20
74:16 135:4	103:12 126:10,23	70:6,13 71:12,12	224:22 259:22	slightly 79:19
192:9 258:1	126:25 127:3	73:17 75:18	261:21	129:17,18 173:9
separated 171:1,5	144:2 159:16	77:25 78:7	situated 1:3,13,14	slowed 134:6
248:3	160:4 168:22	104:12 107:21	2:5	slowing 51:11
separately 126:22	173:6 188:8	113:1,9,19 127:3	situation 118:22	176:8
138:11 149:2	189:17 190:3	145:1 156:20	situational 203:22	small 117:8 125:10
193:20 196:4	192:3 194:22	158:6 159:6,15	six 13:18 179:10	146:18
September 275:20	207:5,23 208:23	160:3,6 162:23	207:12 224:8,14	smaller 127:20
series 68:13 83:17	216:6 260:3	168:10,23 169:3	six-fold 88:2	210:12
141:15 202:11	showed 26:2,5	171:18 185:16	size 197:9	Smith 1:2 8:15
233:9	29:6 43:4,6 69:1	186:21 188:18	Skating 6:25	SmithKline 1:6,18
serious 199:21	71:11 75:17 76:4	199:10 207:8,24	219:22	2:7 8:16,20 9:1
203:15 259:1	139:14 162:19,23	208:23 213:2,5,9	SKB 6:5 64:7	145:11,13 260:25
seriously 42:14	192:5 213:1	227:11 241:16,19	198:13	smoking 136:15
serotonin 121:20	243:4	244:5 246:4,11	Skip 9:4 265:3,25	social 22:8 30:22
126:11 138:14	showing 113:15	significantly 173:7	266:4 269:21	society 146:20
203:11 220:7	139:21 163:16	255:17 268:25	sleep 51:10 175:9	219:20,21
served 190:8	167:9,12 170:1	similar 57:21	slide 13:10,11,17	solicited 112:4
Services 90:18	175:13 187:17	133:10,17 230:17	13:20 16:11,12	somebody 192:14
set 82:20 142:21	222:2	similarly 1:3,13,14	16:16,17 19:24	somewhat 139:18
157:15 158:19	shown 59:4 120:6	2:5	20:3 21:17,23,24	sooner 131:5 262:1
159:21 160:9	120:12 126:15	simple 188:14	22:17 24:10,12	Sop 248:22
197:22 259:7	144:3 191:23	simplicity 211:13	24:13,15,16	sore 154:19
268:6 275:4	240:25	simply 27:2 28:25	25:10,12,12,15	sorry 11:7 18:20
sets 115:4,8 223:8	shows 16:16,18,19	31:5 85:19 97:14	25:16 27:18 31:8	35:5 42:21 45:18
223:9,13	26:12 159:2	165:4 168:14	32:4,17 34:14	52:23 53:23
seven 179:10	Sickness 171:21	169:15,16 186:25	35:16,22 40:21	59:20 65:14
224:14,18	173:19	187:4 188:7	41:2,4,6,10,22	70:17,21,22

73:24 82:24
 87:10 91:1,3 95:9
 95:16 100:21,22
 101:9 106:22
 107:6 118:14
 119:20 121:14
 124:4 139:5
 153:8 157:14
 159:8 161:14
 166:16 176:24
 181:18 183:25
 216:1 217:13,15
 217:23 225:6,6
 227:4 229:19
 232:6 242:16
 244:14 251:19
 256:21 260:16
 267:18 272:10
sort 17:9 44:18
 119:14 120:8,11
 145:21 164:11
 169:11 176:3
 187:5 190:8
 192:17,20
sounded 11:8
sounds 10:15
 130:7
source 39:2 119:14
so-called 16:18
 134:4 139:15
space 156:11
SPAULDING 3:8
speak 31:5 237:8
speaking 171:16
speaks 155:23
specific 95:13
 177:7 192:23
specifically 57:25
 70:15 74:24
speculation 115:2
 115:22 116:24
 121:13 125:16
 137:17 139:12
 140:6 141:2
 143:2 144:10
 145:5 156:6
 161:6 181:8,16
 211:22 213:11
speed 233:11
spend 91:9 106:20

spoken 111:1
sponsored 12:2,3
 64:7,7
sponsors 211:11
sponsor's 92:6,10
spontaneously
 256:16,18,23
 257:12,14,15,16
spring 4:24 35:4,9
 226:16 227:22
square 93:19 232:1
squidge 169:18
SS 221:7
SSRI 116:17 119:6
 145:17,25 177:16
 179:25 180:15
 187:18 220:10,12
 221:7
SSRIs 27:12,17,20
 27:23 29:21
 116:10,13,16,21
 117:13,19 120:2
 120:17 121:6,10
 121:17 126:2,6,7
 127:9 146:2
 147:1 170:19
 181:12 191:22
 192:5 218:3
stabilizers 41:9
staff 18:14 96:20
stamped 100:10
stand 33:8 193:7
standard 272:23
 273:1
standardized
 197:11
standards 161:22
standpoint 191:19
 211:4
stands 250:1
start 108:11,14
 109:12 114:22
 131:5,5,7 164:17
 166:17 267:15
started 108:15
 110:24 134:22
 252:6,12 261:21
 264:10,12
starts 208:7 243:1
state 1:1 2:1 8:13

8:22 13:1 61:2
 179:20 220:5
 253:21
stated 154:14
 159:21 226:15
 241:1 244:24
statement 22:23
 40:22 45:20 46:5
 47:11 94:11
 113:4 116:25
 119:5,9 126:16
 177:20,21 178:1
 186:17 187:21
 248:8 250:23
 262:5
statements 45:23
 193:7 275:8
states 1:10 8:17
 19:25 28:19
 77:16 105:23
 114:25 253:22
stating 61:5
statistical 26:8
 41:18 42:9,23
 46:14 47:1,5,10
 50:4 52:13 53:1
 55:19 60:13
 73:16 75:17 84:2
 157:20 159:17
 169:1,22,24
 185:14 187:6
 191:19 205:9
 227:18 245:18
 247:8 250:7
statistically 26:23
 65:2,4 71:12 78:9
 156:20 158:6
 162:23 168:22
 169:3 171:5,17
 199:10 207:8,23
 208:23 213:2,5,8
 227:10 241:16,19
 244:5 246:11
 248:3 255:17
statistics 143:13
 158:3
Steed 6:4
Steel 2:14
stenographically
 275:9

STI 228:15 229:1
sticker 43:20
stickers 111:8
stipulate 266:25
stipulated 266:23
 274:20,21
stipulating 272:25
stipulation 272:23
 273:5,9,10
 274:17
Stober 50:10
stop 20:10 109:16
 123:8 125:6
 158:8 184:22
 185:20 187:15
 188:21 200:11
 243:17
stopped 11:8
 186:25
straightforward
 37:22 107:20
street 2:15 3:9
 59:9
strength 195:3,15
strengths 196:17
 196:22,25 197:9
stressors 204:3
strike 42:6 45:6
 59:11 60:4 99:15
 99:17 103:21,24
 127:23 132:21
 137:10 141:13
 144:22 149:24
 151:18 156:13
 166:16 178:21
 196:11 266:22
 269:15
Strober 5:11,14
 52:13,15 53:1
 57:19 58:17
 59:18,21,25 60:2
 63:2,4 72:25
 74:12 75:7,13
 76:10 82:4 85:13
 88:15 145:20
 174:12,24 175:3
 176:11 182:25
 231:16
Strober's 53:10
 55:17 175:1

Strober/K 5:16
strokes 137:14
strong 27:1 74:16
 139:24
stronger 76:3
strongly 115:4,24
 122:10 187:24
 245:1 246:13,16
studied 29:4,10
 140:8,9
studies 12:23 29:6
 57:20 58:20 70:3
 70:6 85:9 96:15
 101:22 102:3,4
 105:22 109:6
 113:12,15 121:9
 125:13,18,20
 126:9,14,16,20
 126:21 127:13,14
 127:22,25 135:5
 135:7,15,17
 138:5,6,9 139:13
 139:18,20 140:10
 141:7 142:15,16
 143:6,11,22,23
 143:25 144:1
 146:15,18 149:2
 149:3,12,13,14
 160:2 163:15,19
 166:6 167:8,10
 167:12 172:7,7
 172:10,17,23
 173:18 177:3
 178:22 179:6
 188:1 189:7
 191:10,21,23,25
 192:2,2,3,4,8
 195:11,13 206:22
 207:18 208:17
 212:11 213:17
 215:5,13 221:18
 222:8 225:17
 237:24 238:12
 241:23 243:10
 244:22 246:15
 254:10
study 7:2,6 12:22
 13:2,10,12,13
 16:18 20:4 25:24
 26:14,18,20,21

- 29:8,14 36:23
38:12 41:12
44:17 46:19
50:17,21 54:13
63:9 65:3,11,13
66:9 70:7,14
78:15 82:4,8 83:1
83:7,11,22 85:10
89:22 92:18 94:5
96:10,21 97:20
103:4,9 104:20
106:1,6,7,8
107:15 108:5,10
108:23 109:2
110:10 113:11
120:19,22 121:5
126:3 131:22
132:13 133:13
134:1 135:9
138:11,12 139:15
139:16,19 142:20
142:22 143:12
144:5,14,18,20
144:23,24 145:12
145:17,23,24,24
146:9,13,21
147:2,11,21,25
148:16 149:7,11
149:17,21 150:1
150:10,16,23
151:22 152:14,19
155:11,21 156:15
157:22 158:19
160:1,14,21
162:20 163:10,14
163:17 166:16
167:4,7,8,14,15
167:15,17,17
170:7,11,20,24
171:12 172:15,22
173:6 174:12
175:4 176:18
177:1,8,12,15
178:3,7,9,13,20
179:12,15,19,24
180:14,17 181:23
182:12 184:15
185:3,9,22
187:16 188:8,9
188:12 189:17,19
- 189:20 190:3,4,6
190:10,18 191:4
191:8,16 193:17
194:12 195:3,15
196:15,22 197:8
197:12 198:5,24
199:17,22 203:6
204:14 206:5,9
206:11,25,25
207:1,3,19,20,20
207:22 208:11,14
208:22 209:2
213:9,16,18
218:11,13,15,22
219:11 220:14,18
221:5,6,10,15,22
222:1,3,8,10,16
222:17,18,23
223:4,5,11,14
224:16,20,25
225:7,7,8,10
226:21,25 227:14
227:15 228:11,18
236:10,14,24
237:5,9,17 238:6
238:12,15 239:4
239:10,12,20,22
240:5,8 242:3,22
244:2 245:9,11
246:9,10 250:12
251:12,24 252:5
255:5,8,16,18,21
258:20,25 259:16
259:19 260:15
261:11,21,22
262:2,2,3,9 271:1
271:5,6,15
- studying** 35:8
study's 252:12
stuff 23:19 43:14
72:16 88:18
175:21 192:13
232:19
stupid 103:18
style 19:17
subclinical 165:18
subgroup 92:5
147:8
subgroups 175:12
subinvestigators
- 262:4
subissue 69:18
subject 51:21,23
260:25
subjects 85:9
104:19,21,25
107:14 151:6
171:9 205:18
submission 107:8
107:8,25
submissions
216:11
submit 104:11
submitted 161:9
161:13,14 194:4
197:23 215:3,11
215:16,20,22
216:22 225:1
254:22
subpoena 265:8,12
subscale 157:6
subscales 51:7
subscore 168:21
168:24
subsequent 76:4
77:19 86:2 93:5
122:13 189:7
subsequently
57:24 144:3
238:21
substance 111:3
136:16
substantial 233:6
substantially
268:23
substantive 245:25
272:20
substitute 202:1
subtype 134:5
successfully
150:12
sudden 79:2
267:17
suffer 138:17
256:19
suffering 125:5
167:21
sufficient 85:2
144:25
sugar 157:23,25
- 162:20,24 164:22
171:2 199:13
suggest 59:9 93:3
129:10 197:20
198:1 235:19
236:22 237:3,11
237:18 238:5,9
238:25 239:11,21
suggested 92:2
118:6 138:2
174:24 240:3
243:5
suggesting 125:25
176:21,25 177:8
suggestions 175:1
175:3
suggestive 83:5
suggests 29:21
128:3 132:17
175:5
suicidal 70:9,10,17
70:19 71:13 83:6
131:25 199:6,11
200:16,19 203:17
205:25 206:10
207:8 208:3,3,24
258:17
suicidality 28:20
28:24 29:11 65:5
70:15 71:14
73:17 75:19
76:18 79:7 83:2
83:13 89:23
91:18 92:22
97:25 101:21,24
132:6,24 213:2,7
215:4 226:6
suicidal-related
216:23
suicide 64:21
65:14 71:14 76:6
76:20 78:15 83:6
83:22 84:2 86:25
92:5,7 105:18
109:4 113:19
122:14,16 125:5
125:7,9,10,14
126:1,6,8,12
127:10,15,17
128:2,4 132:15
- 132:18 133:21,22
134:8,9 136:17
136:18,21,24
138:3 200:8
211:18 215:12,12
218:19,21 256:19
suicides 122:17
137:7,7,9,11
suicide-related
83:10 207:6
Suite 2:15 3:5
Suites 2:14
sum 95:5,12 96:9
96:13
summarize 42:3
126:9
summary 25:2
31:15 92:9
193:14
Summary-Effica...
21:7 25:4 31:19
superior 1:1 8:13
14:1,4 20:7,17
21:8,10 25:5,7
31:20,24 41:13
superiority 187:19
220:10,12 221:7
222:2
supplied 7:11
102:21,22
support 88:6
169:18,19 170:6
228:21
supporting 28:25
supports 115:24
suppose 102:13
supposed 19:4,4
sure 13:5 15:6,11
17:12 19:21 21:7
25:4 28:7 31:19
35:7 40:10 64:4
72:7 77:15 78:1
85:5 99:11
105:22 113:25
128:11 129:20
149:18 163:1
189:25 210:5
226:2 234:13
242:24
Surely 188:5

surprising 190:19
Survey 129:15
swap 80:20
switch 66:19
sworn 9:15
symposia 64:7
symposium 4:8
 11:25 234:1
 235:13 236:15
symptom 133:16
 165:6,7
symptomatology
 122:5
symptoms 12:17
 14:3 20:9 21:9
 25:6 27:11 31:22
 133:14,16 134:7
 165:8,16 172:12
 176:16 203:16,21
 211:9
syndrome 165:2
synopsis 41:23
 222:14
systemically 29:5
S.Laden 7:4

T

table 51:18 52:2,3
 52:5 70:11 72:5
 72:11 75:16
 87:14,14,21,25
 152:2,17 155:10
 155:14,19 156:12
 156:14,16,22
 157:10,15 158:4
 158:18 159:16,21
 160:9 162:20
 200:22,25 206:13
 206:16,21 207:12
 207:14,17 241:8
 262:9,10,14,16
 272:2
tables 52:11
 271:12
TADS 139:16,19
tag 24:10,20 25:1
 27:4
tagged 10:14 20:23
 24:3 31:7
tags 10:13 24:9

tail 273:24
take 10:9 18:25
 29:18,22 49:1,6
 49:12 62:10 66:4
 68:3 74:9 77:14
 78:19,21 81:21
 88:7 90:6 98:11
 99:5,6 100:1
 114:15 121:19,22
 155:8 192:6,9
 241:7 242:12
 260:22 264:15,24
 265:19 267:20
 270:5
taken 2:13 49:16
 68:19 109:24
 158:12 201:16
 240:19 249:3
 261:25 268:15
 269:16 275:3,12
takes 123:7
talk 12:13 13:4
 15:12 18:3 21:2
 23:3 27:10 32:18
 40:16 41:23
 42:20 43:13 50:9
 59:1 62:15,18
 64:15 112:21
 136:3,7 145:9
 162:18 199:19
 216:8,20 256:3
 267:9 268:11
talked 46:9,17,18
 50:24 55:23 61:1
 79:23 84:19
 86:10,23 102:2
 102:24 172:9
 243:3 253:20
 256:12
talking 19:24
 27:16 30:17,18
 37:14 49:22
 53:18 54:19
 65:25 69:12 87:2
 87:4 104:10,11
 127:15 132:17
 145:21 176:2
 209:7,9 256:5
 257:1,6,11,18
 260:4 268:4,7,10

talks 20:4 27:7
 75:14 84:11
 92:12 93:4
 105:10,15,17
 130:21 234:12
 238:14 256:2
tape 66:23 67:1
 110:1 158:15
 201:12,15,19
 240:16,21
taper 222:19
tapes 66:22 201:9
targeted 234:7
task 170:9 190:9
TCA 117:25
TCAs 117:15
technical 176:25
teenagers 127:23
 128:1
tell 12:7 28:2 41:17
 42:7,16,22 43:18
 52:23 64:3,20
 81:23 139:5
 152:17 155:9
 159:22 170:8,25
 174:14 183:8
 191:7,15 200:6
 204:18 207:13,13
 215:7 222:9
 233:2 262:17
telling 37:14
tells 152:20
temporal 125:24
ten 112:7 115:20
 183:5 267:21
 268:7,10
tend 44:18
tenured 97:12
term 200:2,18,24
 252:11
terms 10:16 41:12
 117:1,13,15,24
 118:22 136:21
 148:10 161:22
 163:9 165:22
 169:6 173:14
 178:17,20 189:19
 189:21 191:15,21
 192:4,7 193:5
 200:7 202:16

204:25 208:6
 210:20 221:6
 234:16 252:2
 255:24
terns 227:19
terribly 136:3
Terry 212:14
 217:8,10
Test 151:15
testified 9:16 40:1
 46:13 59:22
 60:18 71:9 90:13
 92:20 94:7 98:25
 198:2 225:20
 241:15
testify 59:2,7 61:16
testifying 45:5
 59:20
testimony 60:21,23
 94:19 111:3
 141:19 213:24
 250:1 266:23
 269:16,17 272:16
 272:19 275:6
Texas 4:12 15:7
 22:11 123:18
 124:11
text 79:24 205:20
 243:13
thank 14:6,25
 19:22 23:5,10
 29:25 33:4 42:18
 58:25 60:5 63:12
 89:21 92:20
 106:23 109:7
 110:20 123:3,13
 136:20 138:5
 153:12 203:3
 216:10 223:11
 240:13 263:10
 272:9,12
thanks 18:5 214:9
theory 144:12
Therapeutic
 116:20
therapists 140:22
 141:6,9
therapy 138:20
 139:8,8,17 140:4
 140:8 141:8,10

197:14 211:19,19
thing 25:17 41:24
 94:4 166:5
 169:12 189:4
 190:10 192:22
 222:21 230:3
 240:3 248:21
 252:4
things 41:8,12
 44:18 53:16 55:8
 59:8 70:4,13,15
 70:16 78:5 83:21
 84:18 85:22
 97:18,18 102:9
 134:2,3 136:7
 147:17 150:7
 167:22 169:10,25
 173:7 174:24
 177:6 189:9
 192:9 200:4
 271:22
think 10:11 16:11
 18:16,17 23:6,8
 25:22 31:6 34:10
 37:15 38:5 39:4
 40:8 41:23 42:11
 42:14,15,19,21
 43:3,4,4,5,7,17
 43:22,23,25 44:4
 44:25 45:2 47:16
 47:17 48:12
 51:22 56:2 57:25
 58:7,11 60:18
 69:15,18,20 71:9
 71:14 73:22
 75:21 77:10
 79:13,14,15
 87:11 88:23 90:7
 90:12 92:21 99:2
 99:4 100:7,16
 101:25 102:8
 109:8 114:3,19
 120:8 128:2,4
 129:19 140:12
 142:5 156:9
 169:13,18 170:5
 173:10 187:10
 205:8 214:8,20
 217:1,23 220:21
 223:17 224:12,13

225:19 228:9,10
 228:19 229:23
 232:3 240:15
 242:1,5,7 245:11
 245:11 246:12,23
 247:14 248:11
 249:16,23 252:7
 253:2,2 254:10
 269:1 270:11
 271:19,21,22,23
 273:16
thinking 134:6
 268:9
third 13:25 40:8
 137:8 142:12
 153:23 163:3
 212:25 227:4
 260:5 261:14
Thomas 15:20
 142:1
thorough 213:23
 213:25
thought 9:25 30:7
 32:9 52:23 66:11
 71:19,21 146:19
 165:3 172:15
 173:1,4
thoughts 92:4
 199:6,11 206:1
 206:10 208:3
thousand 265:13
threaten 270:7
three 13:24 16:19
 31:25 43:18
 56:19,22 70:3,6
 137:1 138:1
 147:17 174:3
 181:25 200:22,25
 201:1 206:21
 207:18 220:9
 231:13 254:10
 262:9,14 263:18
 264:5,8 266:2,13
 266:13
three-arm 145:24
throwing 168:18
thrown 33:8
Thursday 2:16 8:1
time 8:11 9:2
 12:24 17:13,14

17:17 25:21,23
 32:10 36:9 37:12
 37:24 39:6 40:8
 41:14 44:15 49:4
 49:14,15,18
 53:19 54:7,9,21
 62:6 66:21,22
 67:2 68:15,17,18
 68:21 72:3,18
 78:14 91:8,10
 97:13,16 102:7
 108:21 109:9,12
 109:23 110:2
 113:11 114:6,10
 115:4,9 118:8
 121:1,5 126:1,7
 129:10 146:14
 148:7 149:23,25
 150:5 158:9,10
 158:14 161:18
 163:17 167:7
 170:7,19 172:21
 173:14 175:12,13
 178:11 184:1
 187:16 190:18
 196:24 201:13,18
 204:23 208:4
 211:6 214:22
 216:21 217:2
 228:12 236:21
 237:2,10,15,22
 238:8 239:9,18
 240:14,17,18,22
 245:22 253:7
 257:1,9 264:1,10
 264:13,16 265:9
 265:12 267:19
 268:2,5,17,20,25
 269:3 274:18,23
 274:24 275:4,5,8
times 13:18 263:23
timing 86:12
title 25:18 124:24
 155:14 206:16
 207:14
titled 11:19 31:19
today 20:13 54:22
 58:25 63:24
 109:10 110:9,21
 113:5 115:20

130:7 209:14
 210:6,11 217:12
 222:6 243:4
 253:21 254:4
Todd 3:8 9:9 110:6
 210:7 215:16
 242:6 263:22
 266:3,15 267:5,8
 273:17,19
Todd's 273:20
told 37:16 38:9,12
 65:1,18 74:16
 78:13,14 84:1
 93:20 166:13,14
 166:18,20 264:3
 267:18
Tonkin 183:18,19
 184:5,13 186:9
Tonkin's 193:6
TONYA 1:13
top 131:21 133:4
 199:23 227:5
 232:11 261:17
topic 72:6 172:20
topics 10:6 11:2
 31:6 110:10
 111:22
torment 204:4
total 34:12 50:2
 57:3,5 96:14,19
 151:6 154:22
 157:8 159:6
 229:12 247:6
totally 30:1
Tower 2:15 8:8
tradition 243:10
train 141:7
trained 141:10
transcribed
 275:10
transcript 273:25
 275:12
Translation
 219:23
trash 243:25 244:1
trashed 241:23
 243:7 244:9,14
trauma 83:4
travel 34:8,12
treat 33:17,21,22

117:10 118:13,14
 118:23 121:6
 138:16 141:11
 143:7 146:23
 164:23 168:12,13
 180:25 188:16,22
 225:2 256:24
treated 114:25,25
 115:5,19,20,25
 135:1,6 146:24
 155:17 159:7,9
 159:13 170:17
 189:9 203:10
 258:8
treating 61:3
 142:23 147:13
 159:24 165:12,23
 169:7 170:2,10
 172:3 173:23
 174:6 175:18,25
 176:23 179:22
 181:4,12 185:18
 186:24 193:1
 218:4
treatment 10:2,24
 10:25,25 12:15
 14:8 20:20 21:11
 22:18 25:8,20
 32:1,6 34:16
 35:18 40:23
 41:14 44:17
 57:20 58:13
 62:22 70:3 113:3
 115:6 116:11
 117:3 120:17
 139:9,24 140:24
 146:20 154:21
 167:18 171:8
 172:25 175:11,14
 177:17 180:1,16
 188:1 192:12
 195:5,17 201:1
 206:18,19 208:4
 208:7,9 222:15
 226:18 227:9
 246:15 251:23
 253:22 255:22
treatments 13:24
 120:7 138:25
 146:16 192:16

trend 126:25
 159:23 160:5
 169:6,20
TREVOR 1:12
trial 8:12 13:23
 64:22 79:4 92:22
 102:4 105:12
 114:10 130:2
 174:3 213:1,4,7
 219:10 227:8,18
 274:19
trials 11:3,4 92:8
 92:10,15 187:17
 216:16 219:23
 220:10
tricyclic 117:2,6
 117:14,24 118:6
 119:2 138:7
 145:25 146:5,17
 187:18 218:20
tricyclics 117:20
 118:13,16 120:11
 163:19 167:9,10
tried 73:22 109:2
 187:11 235:11
 262:17 264:7
trip 34:4
trivial 243:13
true 38:4 51:25
 60:19 177:19,21
 187:21 208:5
 228:18,20 248:7
 249:24 262:5,6
 262:24 264:14
 275:11,19
truly 189:2
truth 187:9,12
truthful 186:16
 254:5
try 59:15 111:21
 138:6 159:10
 178:12 221:15,20
 221:24 259:7
trying 10:11 34:6
 35:2 37:9 44:12
 48:3 57:9,10 60:6
 66:11 118:22
 129:7,9 130:7,24
 131:2,3 132:11
 133:24 147:11

150:11 165:13
 175:20 178:17
 190:11,21,23
 191:7,16 192:7
 221:17 236:11,16
 239:6 244:13
 273:4
turn 51:17 121:23
 142:5 150:25
 170:22 177:10
 193:21 194:8,14
 196:5 206:8
 207:12 209:21
 212:20 220:2
 222:13 227:2,3
 247:19 261:14
turned 173:5
Turning 24:23
turns 189:7
tweak 88:17
twice 272:2
twisting 43:8
two 8:10 16:14
 21:13 31:23 33:1
 43:13 51:24
 52:19 65:16
 66:17 70:3 85:6
 87:23 100:1
 107:18,23 112:8
 112:9 117:15
 118:3,5 128:10
 131:11 132:16
 135:17 137:3
 144:17 147:17
 152:2 153:24
 154:17 155:10
 156:12,14,16,22
 157:10,15 158:15
 158:18,20,23
 159:16,21,22
 162:20 169:21
 176:1,4 180:5
 184:10 185:12
 189:3 192:9
 201:10 203:1
 211:8,25 219:2
 220:11 231:17,19
 238:19 241:20
 243:25 244:1
 247:3,5 250:21

252:20 262:12
 263:12,25 265:15
 265:18,19 267:5
 269:19 272:2
two-day 270:8
two-way 59:9
type 128:5 129:7
 218:15
types 12:18
typically 11:4
 15:13 23:3 131:4
 134:5
typographical
 272:19
T-A-D-S 139:16

U

Uh-huh 261:16
ultimately 65:7
 98:16 160:25
unapproved 236:7
unbates-stamped
 68:10
unblinded 166:5
undergoing 83:12
 140:3
underline 201:25
understand 9:21
 9:23 35:2 37:3
 44:3 48:1 53:7
 57:12 60:9 82:13
 110:13 164:16,18
 166:9 168:6
 180:25 212:12
 227:14 269:6
understanding
 75:25 76:1 79:8
 150:2 252:8
understands
 164:16
understood 110:17
underway 163:20
unethical 42:19,22
 166:21
unfair 43:9
unfortunate 85:15
unfortunately
 85:10 258:19,22
 259:9
unhappy 270:16

uniformly 188:2
unintended 236:5
unipolar 130:21
 131:6
unique 192:1
unit 233:25
United 1:10 8:17
 19:25 105:22
 114:25
university 3:12
 4:11,17 15:7
 22:10 23:17 95:4
 95:25 96:8,23
 97:13 102:25
 104:9 107:3
 123:18 124:10
 133:13 148:25
 165:25 184:5,7
University's
 223:19
unknown 100:10
untimely 141:21
untreated 28:20
 204:5
unusual 143:21
update 82:4,22,25
upper 74:15
uptake 126:5,7
usage 119:12
use 34:14 35:16
 91:19 101:22
 114:9 116:15
 118:25 121:9
 124:18 130:2,14
 138:19 139:7
 145:13 188:7
 189:2,4,8,16
 190:2 197:10
 218:3 233:15
 235:12,20 236:7
 237:12 243:10
 252:11 253:6,11
 254:1,3 259:7
 272:24
useful 136:3
 187:13
uses 233:19 236:8
USX 8:8
utilize 211:5
utilized 174:4

utilizing 245:10

V

vacations 262:8
vague 66:2 79:23
 144:8 184:17
validity 106:1
value 73:17 76:19
 78:7,10,11 127:3
 159:5,14 169:1,3
 169:16 214:6
 244:19 246:5
values 70:13 75:17
 76:25 77:3,25
 78:5 84:16
 159:20 160:4
 185:16 186:21
 188:18
variable 54:17,20
 55:3 165:10,22
 176:22 252:18
 253:6,17
variables 26:10
 43:19 46:10,14
 46:18,25 48:19
 49:22 50:10 52:9
 52:12,25 53:10
 54:5 55:18,21
 56:3,23 57:8,15
 57:19 58:1,4,6,10
 58:11,12 59:15
 59:18 60:7,13
 148:17 155:17,20
 156:3,18,21
 157:9,17 160:11
 167:4 172:1
 173:21 174:5
 175:16 241:13
 244:2 247:9
 248:2 253:15
variance 93:22
variety 203:22
various 72:6 92:3
 185:8 213:4
vary 10:18
vast 223:9,12,22
version 63:7
 217:12 232:8,9
versus 8:15,20,25
 87:1 89:5,12 97:9

145:25,25 157:5
 207:9 208:25
 209:5 210:20
 211:19 269:2
vetting 66:15
vice-chair 107:3,7
vice-versa 107:6
Video 274:23
videographer 8:3
 8:5 9:13 17:11,13
 49:14,17 66:17
 66:21,25 68:17
 68:20 109:22,25
 158:9,13 201:9
 201:13,17 240:17
 240:20 268:13,16
 274:22
Videography 8:6
VIDEOPERAT...
 17:16
videotape 8:10
 201:18
videotapes 201:15
view 22:24 142:14
 142:16 239:7
viewed 165:10
 238:10
virtually 188:2
Vocabulary
 151:15
vs 1:5,17 2:6 92:3

W

W 3:4,13
Wagner 5:12,14
 5:18 15:16,21
 72:24 74:13 75:7
 75:13 76:10 82:4
 82:6 83:12 85:13
 202:20 226:13,17
 226:20 227:17
 228:10,11 243:3
Wagner/G 5:16
wait 20:10 30:1
 115:14 209:23
 215:15 225:18
 264:11
waive 269:7,9
 272:20
waived 272:15

walk 194:12
229:23
wall 22:13
want 26:25 37:22
45:24 48:13 49:9
51:17 52:1 55:6
82:25 84:21 88:6
93:17 94:4,25
98:24 109:12,13
109:19 113:25
123:4 129:20
130:18 142:5
145:9 150:11
169:16 170:14
173:12 177:1,6
190:10 193:21
194:12 222:12
250:2 264:1,4
265:5,9,17
267:11,16
wanted 40:10
69:20 71:1,5
86:15 88:1 93:13
93:18 94:9 107:9
145:23,24 146:18
236:23 237:18
wants 267:5
wasn't 53:21 88:3
99:3,4 130:1,6
132:8 225:20
236:3
watch 61:23
watching 61:12
way 10:12 26:25
30:2 41:24 43:15
73:25 74:5 79:15
86:7,8 93:18
109:3 143:12,13
179:15 180:17
189:21 190:5
193:19 214:3
219:3,4 221:25
228:5,7 232:19
235:19 236:16
238:25 249:11
252:11,15 271:13
272:4
ways 70:14 79:18
163:25 164:9
189:9,12

weak 169:18
254:12
web 39:5 91:6
99:25 100:2
125:21 217:16
224:22
week 13:22 119:1
weekend 147:15
weeks 147:17
week's 119:1
weight 44:21
weightless 139:23
Weintrob 203:3
went 9:24 10:3
95:6 97:1 140:23
170:5 173:9
266:2,13 270:19
weren't 48:11
93:16 103:5
Wetherhold 5:20
82:1
we'll 45:13 46:2,8
66:5 87:7 103:5
114:15 260:4
270:20
we're 17:13 37:18
49:2,3,14,17
55:16 57:8 66:21
68:17 76:11 99:7
109:22,25 168:1
168:16 187:4,7
201:13 210:9
240:15,17 242:5
268:7,10,16
272:11,25 273:12
274:12
we've 12:22 20:13
41:16 42:8 55:22
60:16 61:1 63:16
85:21 100:2,15
114:3 146:4
172:9,11 210:25
230:8
whichever 188:15
188:22
who've 141:7
William 174:23
Williamson 112:13
willing 140:14,15
140:16

Wilshire 3:5
withdrawal 211:10
witness 4:2 7:9
14:20,25 16:10
21:22 26:16
27:22 28:22
29:20 33:1 36:20
37:23 38:17 39:4
39:11,23 41:7,22
43:3 44:3 46:4,22
47:16 48:3,8,15
48:22 49:11,25
50:7 52:1 54:2
55:5,25 57:1
59:24 60:22 61:9
62:3 64:24 67:23
68:8 69:11 71:21
73:24 75:21
79:13 80:6 84:5
90:1,19 93:2
94:17 95:16 96:2
96:6,12 97:4
104:4 106:10
111:23 114:12
115:3,16,23
116:25 118:2
121:14 123:5,7
124:4,6 125:17
135:4 136:1,9
137:18 139:13
140:7 141:4
143:3,10 144:11
145:7 148:4,21
155:24 156:7
158:3 162:15
163:13 172:6
174:20 180:13
183:8 186:5
191:10 197:8
209:11 210:6
211:24 213:12
216:1 217:3
218:6,25 223:21
224:1,5,7,10
227:22 229:19,25
230:5 234:5
235:4,24 240:1
241:9 242:1
247:14 248:11,24
249:5 250:10,19

251:1,15,19
252:14 254:7
258:6 260:7
263:4 265:9
269:4,22 270:8
270:12 271:18
272:8 275:5,6
Women's 184:3
Woodcock 100:19
100:21
word 58:9 78:19
102:13
wording 21:25
words 23:2,3 48:11
69:14,17 145:13
203:4
work 24:15,16,19
25:12,16 27:1,2
38:2,6 47:3 87:20
97:14 136:13,14
140:12 146:1
147:16,18,24
149:1 167:11
168:8,9 189:1,2
214:21 234:13
worked 14:13
44:21 149:12,13
149:14 167:12
207:23
workers 22:9
30:22
works 15:16,21
109:20 148:24
168:17,18 188:25
189:6
world 12:23 36:13
36:25 167:18
168:3,11,19
187:3
worse 43:9 131:22
136:10,11,11
171:17 257:5,20
worsening 207:15
207:24 208:5,8,8
worst 136:1
worth 119:2
wouldn't 53:22
86:7 176:9,12,17
222:1
write 74:16 186:19

writer 262:25
writing 45:10,21
46:6 55:1 82:9
184:1 243:18,19
243:20,21 246:20
written 25:22,24
54:7,9 118:8
143:24 205:21
wrong 16:5 26:12
44:24 71:10
73:25 77:22
159:10 166:14,15
166:19 167:3
174:18 189:12,12
225:19 246:3
272:4
wrongly 188:15,22
wrote 245:22,22
www.depo.com
1:24

Y

year 15:13 31:4
62:19 112:15
127:20 128:4
209:13 220:24
221:1 261:22
years 6:9 56:19
112:7 113:18
115:20 128:23
132:16
yellow 91:25
yesterday 9:24
38:20 46:9 50:9
54:14,23 57:14
64:5 79:23 86:10
86:23 88:4 90:4
92:20 95:7 98:25
99:2 101:25
103:8 110:22
129:25 130:6
194:4 209:12,14
249:18
yo 80:2
young 125:9
younger 127:21
140:8,10
youth 10:2 122:17
126:1 127:10,12
127:13 128:2

188:5 197:15

Z

zero 97:21

zillion 53:15

ZIP 126:5

\$

\$500 34:8,12

\$500,000 96:14

\$541,000 102:25

\$541,017.60 96:23

\$7000 97:16,20

0

0.5 160:2

00590 1:6

01 183:1

01:00:05 119:10

01:00:26 119:15

01:00:37 119:20

01:00:48 119:25

01:00:52 120:1

01:01:05 120:5

01:01:24 120:10

01:01:43 120:15

01:02:05 120:20

01:02:16 120:25

01:02:22 121:1

01:02:31 121:5

01:02:48 121:10

01:03:05 121:15

01:03:24 121:20

01:03:39 121:25

01:03:43 122:1

01:03:52 122:5

01:04:14 122:10

01:04:31 122:15

01:04:46 122:20

01:05:11 122:25

01:05:14 123:1,15

01:06:18 123:5,10

01:06:31 123:20

01:06:39 123:25

124:1

01:06:46 124:5

01:07:01 124:10

01:07:11 124:15

01:07:26 124:20

01:07:33 124:25

125:1,5

01:07:59 125:10

01:08:14 125:15

01:08:24 125:20

01:08:33 125:25

01:08:37 126:1

01:08:50 126:5

01:09:16 126:10

01:09:35 126:15

01:09:37 126:20

01:09:48 126:25

01:09:52 127:1

01:09:59 127:5

01:10:09 127:10

01:10:26 127:15

01:10:33 127:20

01:10:52 127:25

01:10:59 128:1

01:11:20 128:5

01:11:33 128:10

01:11:46 128:15

01:12:05 128:20

01:12:20 128:25

01:12:22 129:1

01:12:24 129:5

01:12:39 129:10

01:12:50 129:15,20

01:13:09 129:25

130:1

01:13:28 130:5

01:13:35 130:10

01:13:37 130:15

01:13:39 130:20

01:13:52 131:1

01:13:59 130:25

01:14:09 131:5

01:14:22 131:10

01:14:24 131:15

01:14:37 131:20

01:14:52 131:25

132:1

01:15:13 132:5

01:15:24 132:10

01:15:35 132:15

01:15:50 132:20

01:16:11 132:25

01:16:16 133:1

01:16:22 133:5

01:16:31 133:10

01:16:43 133:15

01:16:52 133:20

01:17:07 133:25

134:1

01:17:16 134:5

01:17:37 134:10

01:17:46 134:15,20

01:18:14 134:25

01:18:16 135:1

01:18:29 135:5

01:18:46 135:10

01:18:58 135:15

01:19:11 135:20

01:19:26 135:25

136:1

01:19:35 136:5

01:19:44 136:10

01:20:07 136:15

01:20:26 136:20

01:20:46 136:25

01:20:48 137:1

01:21:03 137:5

01:21:28 137:10

01:21:50 137:15

01:22:01 137:20

01:22:11 137:25

138:1

01:22:18 138:5

01:22:59 138:10

01:23:07 138:15

01:23:29 138:20

01:23:39 138:25

01:23:43 139:1

01:23:58 139:5

01:24:16 139:10

01:24:22 139:15

01:24:35 139:20

01:24:50 139:25

01:24:52 140:1

01:25:16 140:5

01:25:29 140:10

01:25:43 140:15

01:25:59 140:20

01:26:09 140:25

01:26:18 141:1

01:26:26 141:5

01:26:37 141:10

01:26:50 141:15

01:27:07 141:20

01:27:28 141:25

01:27:44 142:1

01:28:01 142:5

01:28:11 142:10

01:28:28 142:15

01:28:37 142:20

01:29:01 142:25

143:1

01:29:09 143:5

01:29:16 143:10

01:29:28 143:15

01:29:41 143:20

01:29:58 143:25

01:29:59 144:1

01:30:14 144:5

01:30:26 144:10

01:30:29 144:15

01:30:46 144:20

01:31:13 144:25

145:1

01:31:29 145:5

01:31:44 145:10

01:32:11 145:15

01:32:24 145:20

01:32:41 145:25

01:32:44 146:1

01:32:58 146:5

01:33:13 146:10

01:33:28 146:15

01:33:33 146:20

01:34:09 146:25

147:1

01:34:24 147:5

01:34:39 147:10

01:34:58 147:15

01:35:11 147:20

01:35:26 147:25

01:35:29 148:1

01:35:39 148:5

01:35:50 148:10

01:35:59 148:15

01:36:16 148:20

01:36:43 148:25

01:36:44 149:1

01:36:48 149:5

01:36:59 149:10

01:37:20 149:15

01:37:29 149:20

01:37:43 149:25

01:37:44 150:1

01:37:58 150:5

01:38:13 150:10

01:38:26 150:15

01:38:29 150:20

01:38:50 150:25

01:38:59 151:1

01:39:20 151:5

01:39:33 151:10

01:39:44 151:15

01:40:03 151:20

01:40:18 151:25

01:40:20 152:1

01:40:37 152:5

01:40:52 152:10

01:41:07 152:15

01:41:26 152:20

01:42:29 153:5

01:42:43 153:10

01:42:59 153:15

01:43:20 153:20

01:43:28 153:25

01:43:31 154:1

01:43:46 154:5

01:44:03 154:10

01:44:24 154:15

01:44:33 154:20

01:45:01 154:25

01:45:05 155:1

01:45:24 155:5

01:46:01 155:10

01:46:41 155:15

01:46:50 155:20

01:47:07 156:1

01:47:14 156:5

01:47:24 156:10

01:47:39 156:15

01:47:58 156:20

01:48:18 156:25

157:1

01:48:20 157:5

01:48:52 157:10

01:49:26 157:15

01:49:41 157:20

01:49:50 157:25

01:50:09 158:1

01:50:16 158:5

01:50:24 158:10

01:56:35 158:15

01:56:48 158:20

01:57:11 158:25

01:57:13 159:1

01:57:26 159:5

01:57:52 159:10	02:08:43 167:25	02:20:33 176:5	02:32:14 184:25	02:42:37 193:10
01:58:05 159:15	02:08:50 168:1	02:20:50 176:10	185:1	02:44:22 193:15
01:58:22 159:20	02:09:05 168:5	02:21:05 176:15	02:32:24 185:5	02:44:48 193:20
01:58:37 159:25	02:09:16 168:10	02:21:24 176:20	02:32:37 185:10	02:45:13 193:25
01:58:39 160:1	02:09:33 168:15	02:21:41 176:25	02:32:58 185:15	02:45:14 194:1
01:58:58 160:5	02:09:48 168:20	02:21:43 177:1	02:33:13 185:20	02:45:22 194:5
01:59:11 160:10	02:10:09 168:25	02:21:59 177:5	02:33:20 185:25	02:45:31 194:10
01:59:20 160:15	169:1	02:22:11 177:10	02:33:35 186:1	02:45:48 194:15
01:59:39 160:20	02:10:22 169:5	02:22:26 177:15	02:33:43 186:5	02:46:05 194:20
01:59:48 160:25	02:10:35 169:10	02:22:41 177:20	02:33:50 186:10	02:46:11 194:25
01:59:58 161:1	02:10:50 169:15	02:22:46 177:25	02:34:20 186:15	195:1
02:00:01 161:5	02:11:11 169:20	02:22:52 178:1	02:34:37 186:20	02:46:18 195:5
02:00:13 161:10	02:11:29 169:25	02:23:05 178:5	02:34:48 186:25	02:46:29 195:10
02:00:31 161:15	02:11:35 170:1	02:23:22 178:10	02:34:52 187:1	02:46:41 195:15
02:00:52 161:20	02:11:46 170:5	02:23:33 178:15	02:35:05 187:5	02:47:24 195:20
02:01:07 161:25	02:12:07 170:10	02:23:41 178:20	02:35:14 187:10	02:47:32 30:5
162:1	02:12:37 170:15	02:24:07 178:25	02:35:35 187:15	88:10 103:15
02:01:20 162:5	02:12:58 170:20	02:24:11 179:1	02:35:43 187:20	106:15 111:10
02:01:35 162:10	02:13:28 170:25	02:24:20 179:5	02:36:03 187:25	152:25 182:5
02:01:52 162:15	02:13:31 171:1	02:24:33 179:10	02:36:07 188:1	201:20 242:10
02:02:01 162:20	02:13:44 171:5	02:25:03 179:15	02:36:16 188:5	260:20
02:02:18 162:25	02:13:48 171:10	02:25:35 179:20	02:36:31 188:10	02:47:46 195:25
02:02:20 163:1	02:14:11 171:15	02:26:03 179:25	02:36:35 188:15	02:47:52 196:1
02:02:31 163:5	02:14:24 171:20	02:26:07 180:1	02:37:01 188:20	02:48:16 196:5
02:02:58 163:10	02:14:46 171:25	02:26:13 180:5	02:37:16 188:25	02:48:28 196:10
02:03:07 163:15	02:14:48 172:1	02:26:22 180:10	02:37:20 189:1	02:48:44 196:15
02:03:20 163:20	02:15:07 172:5	02:26:31 180:15	02:37:22 189:5	02:49:07 196:20
02:03:35 163:25	02:15:37 172:10	02:26:48 180:20	02:37:41 189:10	02:49:14 196:25
164:1	02:15:44 172:15	02:26:59 180:25	02:37:59 189:15	197:1
02:03:58 164:5	02:15:50 172:20	02:27:07 181:1	02:38:16 189:20	02:49:24 197:5
02:04:05 164:10	02:16:05 172:25	02:27:37 181:5	02:38:28 189:25	02:49:31 197:10
02:04:20 164:15	02:16:13 173:1	02:27:46 181:10	02:38:33 190:1	02:49:43 197:15
02:04:29 164:20	02:16:24 173:5	02:27:48 181:15	02:38:48 190:5	02:49:58 197:20
02:04:52 164:25	02:16:43 173:10	02:27:50 181:20	02:39:09 190:10	02:50:18 197:25
165:1	02:16:44 173:15	02:28:05 181:25	02:39:18 190:15	198:1
02:05:11 165:5	02:17:03 173:20	02:28:07 182:1	02:39:35 190:20	02:50:48 198:5
02:05:24 165:10	02:17:26 173:25	02:28:39 182:10	02:39:52 190:25	02:51:03 198:10
02:05:41 165:15	174:1	02:29:07 182:15	02:39:59 191:1	02:51:24 198:15
02:06:01 165:20	02:17:37 174:5	02:29:18 182:20	02:40:09 191:5	02:51:43 198:20
02:06:14 165:25	02:18:16 174:10	02:29:48 182:25	02:40:16 191:10	02:51:58 198:25
02:06:18 166:1	02:18:33 174:15	02:30:01 183:1	02:40:28 191:15	02:52:03 199:1
02:06:26 166:5	02:18:39 174:20	02:30:14 183:5	02:40:39 191:20	02:52:07 199:5
02:06:41 166:10	02:18:58 174:25	02:30:22 183:10	02:40:58 191:25	02:52:18 199:10
02:07:09 166:15	175:1	02:30:35 183:15	02:40:59 192:1	02:52:37 199:15
02:07:22 166:20	02:19:11 175:5	02:30:43 183:20	02:41:07 192:5	02:53:01 199:20
02:07:37 167:1	02:19:24 175:10	02:30:52 183:25	02:41:09 192:10	02:53:22 199:25
02:07:46 167:5	02:19:44 175:15	02:30:59 184:1	02:41:11 192:15,20	02:53:26 200:1
02:08:01 167:10	02:20:11 175:20	02:31:05 184:5	02:42:11 192:25	02:53:43 200:5
02:08:13 167:15	02:20:24 175:25	02:31:28 184:10	193:1	02:54:01 200:10,15
02:08:31 167:20	02:20:26 176:1	02:31:44 184:15	02:42:18 193:5	02:54:20 200:20

02:54:46 200:25 201:1	03:13:37 209:20	03:26:13 218:10	03:39:52 226:25	03:53:11 235:20
02:55:05 201:5	03:13:46 209:25	03:26:37 218:15	03:39:59 227:1	03:53:28 235:25 236:1
02:56:14 201:10	03:13:48 210:1	03:26:44 218:20	03:40:18 227:5	03:53:39 236:5
02:56:18 201:15	03:14:11 210:5	03:27:09 218:25	03:40:29 227:10	03:53:48 236:10
03:02:59 201:25 202:1	03:14:46 210:15	03:27:11 219:1	03:40:46 227:15	03:54:07 236:15
03:03:13 202:5	03:15:52 210:20	03:27:22 219:5	03:41:05 227:20	03:54:22 236:20
03:03:31 202:10	03:16:11 210:25	03:27:39 219:10	03:41:13 228:1	03:54:33 236:25
03:03:48 202:15	03:16:14 211:1	03:28:16 219:15	03:41:20 228:5	03:54:35 237:1
03:04:05 202:20	03:16:31 211:5	03:28:37 219:20	03:41:29 228:10	03:54:58 237:5
03:04:20 202:25 203:1	03:16:41 211:10	03:28:50 219:25	03:41:43 228:15	03:55:16 237:10
03:04:28 203:5,10	03:17:05 211:15	03:29:01 220:1	03:42:11 228:20	03:55:33 237:15
03:05:01 203:15	03:17:20 211:20	03:29:11 220:5	03:42:22 228:25	03:55:48 237:20
03:05:14 203:20	03:17:24 211:25 212:1	03:29:22 220:10	03:42:24 229:1	03:56:09 237:25
03:05:24 203:25	03:17:41 212:5	03:29:35 220:15	03:42:37 229:5	03:56:14 238:1
03:05:26 204:1	03:18:03 212:10	03:30:03 220:20	03:42:48 229:10	03:56:18 238:5
03:05:31 204:5	03:18:24 212:15	03:30:13 220:25	03:44:22 229:15	03:56:29 238:10
03:05:46 204:10	03:18:24 212:15	03:30:14 221:1	03:45:46 229:20	03:56:44 238:15
03:06:13 204:15	03:18:35 212:20	03:30:24 221:5	03:45:50 229:25 230:1,5	03:56:59 238:20
03:06:20 204:20	03:18:46 212:25 213:1	03:30:50 221:10	03:46:43 230:10	03:57:11 238:25 239:1
03:06:31 204:25 205:1	03:18:59 213:5	03:31:05 221:15	03:47:07 230:15	03:57:24 239:5
03:06:46 205:5	03:19:22 213:10	03:31:14 221:20	03:47:28 230:20,25	03:57:44 239:10
03:07:07 205:10	03:19:33 213:15	03:31:22 221:25	03:47:29 231:1	03:58:13 239:15
03:07:22 205:15,20	03:19:44 213:20	03:31:28 222:1	03:47:41 231:5	03:58:18 239:20
03:07:46 205:25 206:1	03:20:03 213:25	03:31:58 222:5	03:47:46 231:10	03:58:37 239:25
03:08:09 206:5	03:20:07 214:1	03:32:20 222:10	03:47:59 231:15	03:58:41 240:1
03:08:35 206:10	03:20:18 214:5	03:32:43 222:15	03:48:13 231:20	03:58:44 240:5
03:08:58 206:15	03:20:46 214:10,15	03:33:05 222:20	03:48:20 231:25 232:1	03:59:01 240:10
03:09:16 206:20	03:21:11 214:20	03:33:26 222:25	03:48:29 232:5	04 1:6 217:24,25 218:1
03:09:33 206:25	03:21:28 214:25	03:33:28 223:1	03:48:46 232:10	04-CC-00590 8:14
03:09:35 207:1	03:21:29 215:1	03:33:39 223:5	03:49:09 232:15	04:07:16 240:15
03:09:50 207:5	03:21:52 215:5	03:33:58 223:10	03:49:22 232:20	04:07:50 240:20
03:10:07 207:10	03:22:01 215:10	03:34:20 223:15	03:49:37 232:25	04:08:07 240:25
03:10:18 207:15	03:22:13 215:15	03:34:35 223:20	03:49:43 233:1	04:08:11 241:1
03:10:29 207:20	03:22:24 215:20	03:34:39 223:25	03:49:58 233:5	04:08:14 241:5
03:10:58 207:25	03:22:33 215:25	03:34:48 224:1,5 224:10	03:50:18 233:10	04:08:24 241:10
03:11:01 208:1	03:22:37 216:1	03:35:20 224:15	03:50:48 233:20	04:08:37 241:15
03:11:14 208:5	03:23:22 216:5	03:35:37 224:20	03:51:01 233:25	04:08:50 241:20
03:11:29 208:10	03:23:35 216:10	03:36:26 224:25	03:51:07 234:1	04:09:16 241:25 242:1
03:11:43 208:15	03:23:58 216:15	03:36:33 225:1	03:51:20 234:5	04:09:50 242:5
03:12:03 208:20	03:24:20 216:20	03:36:44 225:5	03:51:33 234:10	04:10:18 242:15
03:12:20 208:25	03:24:33 216:25 217:1	03:36:58 225:10	03:51:50 234:15	04:10:37 242:20
03:12:24 209:1	03:24:48 217:5	03:37:13 225:15	03:52:07 234:20	04:10:58 242:25 243:1
03:12:41 209:5	03:25:07 217:10	03:37:14 225:20	03:52:18 234:25	04:11:01 243:5
03:13:05 209:10	03:25:18 217:15	03:37:35 225:25	03:52:22 235:1	04:11:09 243:10
03:13:22 209:15	03:25:26 217:20	03:37:48 226:1	03:52:35 235:5	04:11:33 243:15
	03:25:44 217:25 218:1	03:38:52 226:5	03:52:44 235:10	
	03:26:11 218:5	03:39:09 226:10	03:52:58 235:15	
		03:39:28 226:15		
		03:39:41 226:20		

04:11:39 243:20	04:22:46 252:15	261:1	04:42:58 269:20	09:17:43 11:25
04:11:46 243:25	04:23:03 252:20	04:34:18 261:5	04:43:01 269:25	09:17:44 12:1
04:11:50 244:1	04:23:18 252:25	04:34:28 261:10	270:1	09:17:50 12:5
04:12:07 244:5	04:23:20 253:1	04:34:35 261:15	04:43:16 270:5	09:18:11 12:10
04:12:22 244:10	04:23:31 253:5	04:34:39 261:20	04:43:24 270:10	09:18:20 12:15
04:12:31 244:15	04:23:48 253:10	04:34:44 261:25	04:43:26 270:15	09:18:33 12:20
04:12:44 244:20	04:24:03 253:15	04:34:50 262:1	04:43:37 270:20	09:18:48 12:25
04:12:52 244:25	04:24:22 253:20	04:35:05 262:5	04:43:39 270:25	09:18:50 13:1
04:13:01 245:1	04:24:26 253:25	04:35:24 262:10	04:43:41 271:1	09:18:59 13:5
04:13:11 245:5	04:24:35 254:1	04:35:41 262:15	04:43:59 271:5	09:19:05 13:10
04:13:16 245:10	04:24:50 254:5	04:35:50 262:20	04:44:16 271:10	09:19:16 13:15
04:13:35 245:15	04:24:52 254:10	04:36:14 262:25	04:44:29 271:15	09:19:29 13:20
04:13:43 245:20	04:25:13 254:15	263:1	04:44:39 271:20	09:19:41 13:25
04:13:58 245:25	04:27:03 254:20	04:36:28 263:5	04:44:46 271:25	09:19:44 14:1
246:1	04:27:13 254:25	04:36:31 263:10	04:44:48 272:1	09:20:01 14:5
04:14:18 246:5	04:27:14 255:1	04:36:46 263:15	04:45:11 272:5	09:20:11 14:10
04:14:28 246:10	04:27:20 255:5	04:36:58 263:20,25	04:45:20 272:10	09:20:22 14:15
04:14:41 246:15	04:27:39 255:10	04:36:59 264:1	04:45:24 272:15	09:20:28 14:20,25
04:14:50 246:20	04:27:46 255:15	04:37:09 264:5	04:45:33 272:20	15:1
04:15:09 246:25	04:28:07 255:20	04:37:16 264:10	04:45:48 272:25	09:20:35 15:5
247:1	04:28:18 255:25	04:37:28 264:15	273:1	09:20:44 15:10
04:15:18 247:5	04:28:20 256:1	04:37:31 264:20	04:45:52 273:5	09:21:07 15:15
04:15:31 247:10	04:28:29 256:5	04:37:37 264:25	04:46:13 273:10	09:21:14 15:20
04:15:39 247:15	04:28:33 256:10	265:1	04:46:26 273:15	09:21:28 15:25
04:15:58 247:20	04:28:43 256:15	04:37:41 265:5	04:46:41 273:20	09:21:29 16:1
04:16:03 247:25	04:28:59 256:20	04:37:59 265:10	04:46:48 273:25	09:21:31 16:5
04:16:14 248:1	04:29:09 256:25	04:38:01 265:15	04:46:58 274:1	09:21:48 16:10
04:16:29 248:5	04:29:11 257:1	04:38:11 265:20	04:47:03 274:5	09:22:07 16:15
04:16:31 248:10	04:29:20 257:5	04:38:18 265:25	04:47:14 274:10	09:22:18 16:20
04:17:31 248:15	04:29:33 257:10	04:38:20 266:1,5	04:47:20 274:15	09:22:33 16:25
04:18:13 248:20	04:29:46 257:15	04:38:33 266:10	04:47:24 274:20	17:1
04:18:28 249:1	04:29:59 257:20	04:38:37 266:15	05 159:5 185:13	09:22:35 17:5
04:18:33 249:5	04:30:11 257:25	04:38:44 266:20	06-1247JD 8:19	09:22:44 17:10
04:19:05 249:10	04:30:16 258:1	04:38:52 266:25	06-1247-JD 1:17	09:23:26 17:15
04:19:09 249:15	04:30:35 258:5	267:1	06:59:58 184:20	09:24:05 17:20
04:19:31 249:20	04:30:46 258:10	04:39:05 267:5	07 169:1	09:24:31 17:25
04:19:41 249:25	04:31:01 258:15	04:39:16 267:10	07:59:58 210:10	18:1
04:19:44 250:1	04:31:13 258:20	04:39:24 267:15	09 169:4	09:24:58 18:5
04:19:48 250:5	04:31:16 258:25	04:39:33 267:20	09:14:33 9:20	09:25:11 18:10
04:20:22 250:10	259:1	04:39:46 267:25	09:14:44 9:25 10:1	09:25:24 18:15
04:20:33 250:15	04:31:39 259:5	268:1	09:14:58 10:5	09:25:35 18:20
04:20:39 250:20	04:31:50 259:10	04:39:50 268:5	09:15:13 10:10	09:25:39 18:25
04:20:46 250:25	04:32:05 259:15	04:40:09 268:10	09:15:33 10:15	19:1
04:20:48 251:1	04:32:16 259:20	04:40:18 268:15	09:15:50 10:20	09:25:52 19:5
04:21:03 251:5	04:32:28 259:25	04:41:48 268:20	09:16:05 10:25	09:26:05 19:10
04:21:16 251:10	04:32:29 260:1	04:42:05 268:25	11:1	09:26:28 19:15
04:22:01 251:15,20	04:32:39 260:5	04:42:09 269:1	09:16:16 11:5	09:26:41 19:20
04:22:16 252:1	04:32:41 260:10	04:42:18 269:5	09:16:22 11:10	09:27:11 19:25
04:22:26 252:5	04:33:37 260:15	04:42:29 269:10	09:17:16 11:15	09:27:14 20:1
04:22:39 252:10	04:34:05 260:25	04:42:39 269:15	09:17:35 11:20	09:27:22 20:5

09:27:29 20:10	09:37:01 28:25	09:46:20 37:20	09:53:37 46:5	10:07:20 51:15
09:27:35 20:15	09:37:03 29:1	09:46:33 37:25	09:53:43 46:10	10:07:52 51:20
09:27:37 20:20	09:37:09 29:5	09:46:35 38:1	09:53:59 46:15	10:08:03 51:25
09:27:46 20:25	09:37:16 29:10	09:46:44 38:5	09:54:11 46:20	52:1
21:1	09:37:28 29:15	09:46:50 38:10	09:54:16 46:25	10:08:09 52:5
09:27:58 21:5	09:37:41 29:20	09:46:59 38:15	09:54:18 47:1	10:08:24 52:10
09:27:59 21:10	09:38:29 29:25	09:47:07 38:20	09:54:28 47:5	10:08:44 52:15
09:28:16 21:15	30:1	09:47:18 38:25	09:54:39 47:10	10:08:59 52:20
09:28:22 21:20	09:38:31 30:10	39:1	09:54:50 47:15	10:09:07 52:25
09:28:37 21:25	09:38:43 30:15	09:47:28 39:5	09:55:03 47:20	10:09:13 53:1
09:28:41 22:1	09:38:59 30:20	09:47:41 39:10	09:55:11 47:25	10:09:22 53:5
09:28:48 22:5	09:39:07 30:25	09:47:43 39:15	48:1	10:09:29 53:10
09:28:52 22:10	09:39:11 31:1	09:47:48 39:20	09:55:16 48:5	10:09:44 53:15
09:29:03 22:15	09:39:28 31:5	09:48:03 39:25	09:55:39 48:15,20	10:10:05 53:20
09:29:20 22:20	09:39:37 31:10	40:1	48:25 49:1,5,10	10:10:16 54:1
09:29:24 22:25	09:39:43 31:15,20	09:48:07 40:5	09:55:52 49:15	10:10:18 54:5
23:1	09:39:50 31:25	09:48:11 40:10		10:10:28 54:10
09:31:20 23:5,10	32:1	09:48:20 40:15	1	10:10:39 54:15
09:31:43 23:15	09:40:11 32:5	09:48:28 40:20	1 6:9 66:23 92:8	10:10:58 54:20
09:32:01 23:20	09:40:24 32:10	09:48:46 41:1	111:11,14 112:21	10:11:05 54:25
09:32:14 23:25	09:40:50 32:15	09:48:58 41:5	112:23 129:11	55:1
09:32:16 24:1	09:41:07 32:20	09:49:05 41:10	141:24 154:18	10:11:18 55:5
09:32:26 24:5	09:41:14 32:25	09:49:20 41:15	157:5 163:6	10:11:24 55:10
09:32:31 24:10	09:41:18 33:1	09:49:28 41:20	165:21 166:6,10	10:11:26 55:15
09:32:44 24:15	09:41:26 33:5	09:49:41 41:25	183:11 184:25	10:11:44 55:20
09:33:01 24:20	09:41:33 33:10	09:49:43 42:1	203:15 223:22	10:11:59 55:25
09:33:05 24:25	09:41:44 33:15	09:49:50 42:5	1-100 1:8	56:1
09:33:07 25:1	09:42:03 33:20	09:50:01 42:10	1/30/04 5:24	10:12:13 56:5
09:33:14 25:5	09:42:14 33:25	09:50:16 42:15	1/5/06 5:22	10:12:14 56:10
09:33:29 25:10	09:42:18 34:1	09:50:29 42:20	1:51 158:10	10:12:24 56:15
09:33:35 25:15	09:42:24 34:5	09:50:46 42:25	1:57 158:14	10:12:39 56:20
09:34:03 25:20	09:42:43 34:10	09:50:48 43:1	10 6:9,19 15:13	10:12:52 56:25
09:34:11 25:25	09:42:52 34:15	09:51:03 43:5	31:4 70:11,11	57:1
26:1	09:43:18 34:20	09:51:14 43:10	72:5,11 75:16	10:13:01 57:5
09:34:18 26:5	09:43:37 34:25	09:51:26 43:15	83:4,7,11 127:19	10:13:05 57:10
09:34:26 26:10	09:43:39 35:1	09:51:37 43:20	182:18,21 203:16	10:13:09 57:15
09:34:37 26:15	09:44:03 35:5	09:51:59 43:25	204:8	10:13:33 57:20
09:34:41 26:20	09:44:05 35:10	09:52:01 44:1	10-year 126:4	10:13:52 57:25
09:34:58 26:25	09:44:18 35:15	09:52:07 44:5	10/03/98 4:14	10:13:58 58:1
09:34:59 27:1	09:44:33 35:20	09:52:14 44:10	10:05:43 49:20	10:14:13 58:5
09:35:11 27:5	09:44:44 36:1	09:52:20 44:15	10:06:13 49:25	10:14:28 58:10,15
09:35:18 27:10	09:45:16 36:5	09:52:35 44:20	50:1	10:14:35 58:20
09:35:29 27:15	09:45:29 36:10	09:52:50 44:25	10:06:22 50:5	10:14:59 58:25
09:35:46 27:20	09:45:41 36:15	09:52:52 45:1	10:06:26 50:10	59:1
09:35:59 27:25	09:45:44 36:20	09:52:58 45:5	10:06:31 50:15	10:15:11 59:5
09:36:03 28:1	09:45:58 36:25	09:53:03 45:10	10:06:44 50:20	10:15:14 59:10
09:36:11 28:5	37:1	09:53:11 45:15	10:06:58 50:25	10:15:26 59:15
09:36:14 28:10	09:46:07 37:5	09:53:18 45:20	10:06:59 51:1	10:15:35 59:20
09:36:33 28:15	09:46:09 37:10	09:53:26 45:25	10:07 49:18	10:15:43 59:25
09:36:44 28:20	09:46:16 37:15	46:1	10:07:03 51:5,10	10:15:44 60:1

10:15:59 60:5	10:31 68:18	10:51:20 76:25	55:22 57:14	11:12:01 91:15
10:16:14 60:10	10:42:20 68:20	10:51:24 77:1	159:5 193:10,13	11:12:03 91:20
10:16:28 60:15,20	10:42:29 68:25	10:51:29 77:5	203:14 231:1	11:12:22 91:25
10:16:39 60:25	10:42:33 69:1	10:51:33 77:10	269:2	11:12:24 92:1
10:16:41 61:1	10:42:46 69:5	10:52:01 77:15	11-19-95 6:1	11:12:31 92:5,10
10:17:01 61:5	10:43 68:21	10:52:24 77:20	11-8-02 6:2	11:12:35 92:15
10:17:14 61:10	10:43:01 69:15	10:52:39 77:25	11/24/98 5:3	11:12:41 92:20
10:17:31 61:15	10:43:03 69:10	78:1	11:00 86:13	11:13:20 92:25
10:17:33 61:20	10:43:20 69:20	10:52:52 78:5	11:00:05 84:5	93:1
10:17:58 61:25	10:43:28 69:25	10:53:09 78:10	11:00:09 84:10	11:13:35 93:5
62:1	10:43:29 70:1	10:53:24 78:15	11:00:16 84:15	11:13:50 93:10
10:18:11 62:5	10:43:52 70:5	10:53:52 78:20	11:00:18 84:20	11:14:07 93:15
10:18:16 62:10	10:44:13 70:10	10:53:59 78:25	11:00:24 84:25	11:14:20 93:20
10:18:37 62:15	10:44:35 70:15	79:1	11:00:28 85:1	11:14:29 93:25
10:18:50 62:20	10:44:50 70:20	10:54:13 79:5	11:00:41 85:5	11:14:31 94:1
10:19:13 62:25	10:45:09 70:25	10:54:22 79:10	11:00:50 85:10	11:14:43 94:5
10:19:16 63:1,5,10	10:45:11 71:1	10:54:29 79:15	11:01:05 85:15	11:15:03 94:10
10:20:01 63:15	10:45:18 71:5	10:54:44 79:20	11:01:16 85:20	11:15:13 94:15
10:20:03 63:20	10:45:28 71:10	10:54:59 79:25	11:01:26 85:25	11:15:20 94:20
10:20:14 63:25	10:45:48 71:15	10:55:05 80:1	11:01:28 86:1	11:15:28 94:25
10:20:16 64:1	10:46:01 71:20	10:55:09 80:5	11:01:41 86:5	11:15:31 95:1
10:20:18 64:5	10:46:07 71:25	10:55:16 80:10	11:01:48 86:10	11:15:43 95:5
10:20:39 64:10	10:46:09 72:1	10:55:28 80:15	11:02:20 86:15	11:15:44 95:10
10:20:50 64:15	10:46:18 72:5	10:55:37 80:20,25	11:02:33 86:20	11:15:59 95:15
10:21:09 64:20	10:46:35 72:10	10:55:46 81:1	11:02:37 86:25	11:16:05 95:20
10:21:20 64:25	10:46:41 72:15	10:55:48 81:5	11:02:48 87:1	11:16:13 95:25
65:1	10:46:59 72:20	10:56:50 81:10	11:02:59 87:5	96:1,5
10:21:33 65:5	10:47:14 72:25	10:56:59 81:15	11:03:09 87:10	11:16:24 96:10
10:21:41 65:10	10:47:20 73:1	10:57:11 81:20	11:03:16 87:15	11:16:43 96:15
10:21:48 65:15	10:47:35 73:5	10:57:16 81:25	11:03:33 87:20	11:16:48 96:20
10:22:13 65:20	10:47:41 73:10	10:57:22 82:1	11:03:43 87:25	11:17:03 96:25
10:22:22 65:25	10:47:50 73:15	10:57:33 82:5	11:03:48 88:1	97:1
66:1	10:48:03 73:20	10:57:59 82:10	11:04:03 88:5	11:17:13 97:5
10:22:26 66:5	10:48:11 73:25	10:58:09 82:15	11:06:44 88:15	11:17:22 97:10
10:22:39 66:10	74:1	10:58:18 82:20	11:07:07 88:20	11:17:31 97:15
10:22:41 66:15	10:48:18 74:5	10:58:33 82:25	11:07:09 88:25	11:17:43 97:20
10:23:20 66:20	10:48:28 74:10,15	10:58:35 83:1	11:07:11 89:1	11:18:05 97:25
10:24 66:23	10:48:39 74:20	10:58:41 83:5	11:07:16 89:5	98:1
10:26:11 66:25	10:48:59 74:25	10:59:03 83:10	11:07:33 89:10	11:18:07 98:5
10:26:13 67:1	10:49:01 75:1	10:59:16 83:15	11:07:59 89:15	11:18:16 98:10
10:26:24 67:5	10:49:11 75:5	10:59:28 83:20	11:08:13 89:20	11:18:20 98:15
10:26:48 67:10	10:49:28 75:10	10:59:50 83:25	11:08:22 90:1	11:18:37 98:20
10:26:50 67:15	10:49:46 75:15	84:1	11:08:26 89:25	11:18:41 98:25
10:26:58 67:20	10:50:03 75:20	100,000 127:19	11:09:01 90:5	11:18:44 99:1
10:27 67:2	10:50:14 75:25	103 6:1	11:09:16 90:10,15	11:18:58 99:5
10:27:11 67:25	10:50:18 76:1	106 6:2,4	11:10:09 90:20	11:19:28 99:10
10:27:14 68:1	10:50:24 76:5	109 4:5	11:11:22 90:25	11:19:33 99:15
10:28:05 68:5	10:50:41 76:10	1099s 102:1	11:11:24 91:1	11:19:52 99:20
10:28:13 68:10	10:50:59 76:15	11 4:8 6:20 46:10	11:11:29 91:5	11:20:03 99:25
10:28:33 68:15	10:51:11 76:20	47:11,18,21 48:3	11:11:50 91:10	100:1

11:20:05 100:5	11:30:18 108:20	12:56:05 116:5	18 7:3 107:15	20 7:6 15:13 128:3
11:20:16 100:10	11:30:41 108:25	12:56:20 116:10	129:11 138:7	129:6,11 141:15
11:20:58 100:15	11:30:43 109:1	12:56:33 116:15	152:9,23 159:7	141:17 179:3
11:21:11 100:20	11:30:52 109:5	12:56:50 116:20	229:14,15 230:4	198:9 229:14
11:21:22 100:25	11:31:09 109:10,15	12:57:13 116:25	230:5,14	230:9 232:3,4
101:1	109:20	117:1	18.11 152:4	2000 4:20,22 30:12
11:21:37 101:5	11:32 109:23	12:57:14 117:5	18.24 159:9	32:19,25 33:2,7
11:21:50 101:10	11:59:58 48:10	12:57:26 117:10	18.6 152:6	2001 4:24 5:2 35:4
11:22:09 101:15	111 6:9	12:57:43 117:15	18.97 152:4	35:10,20 36:8
11:22:14 101:20	1180 3:9	12:58:05 117:20	18.99 152:3	62:17 126:4
11:22:28 101:25	12 6:21 151:7,24	12:58:24 117:25	182 6:18,19	185:25 203:7
11:22:29 102:1	152:22 195:19,22	12:58:29 118:1	19 4:16 7:4 216:8	220:11 222:20,25
11:22:31 102:5	12-98 7:2	12:58:41 118:5	229:14,16,21	223:11,14,25
11:22:33 102:10	12:00 109:10,11,13	12:58:59 118:10	230:8,23	224:2,2,17
11:23:14 102:15	12:30 109:10	12:59:09 118:15	192 132:14	2002 5:6 64:6
11:23:16 102:20	12:49:43 109:25	12:59:22 118:20	193 6:20	183:12 202:5
11:23:22 102:25	12:49:44 110:1	12:59:35 118:25	195 6:21	215:17,20 219:20
11:23:28 103:1	12:49:58 110:5	12:59:41 119:1	1989 116:17 119:6	220:25 224:7,25
11:23:39 103:5	12:50:09 110:10	12:59:48 119:5	1990 220:13,15	242:20
11:23:52 103:10	12:50:24 110:15,20	121 8:6	1991 126:4	2003 33:3 91:20
11:24:07 103:20	12:50:29 110:25	12100 3:5	1994 116:12,17,20	92:2 186:6
11:24:11 103:25	12:50:31 111:1	122 6:11,12,13,14	119:6 209:22	215:13,22 216:8
11:24:16 104:1	12:50:43 111:5	13 6:23 18:2 50:15	1995 104:13,22	216:20 226:17
11:24:35 104:5	12:51 110:2	63:4 159:14	231:2	227:22
11:24:48 104:10	12:51:13 111:15	174:10 201:21,24	1996 107:4 112:6	2004 90:18 93:11
11:25:16 104:15	12:51:58 111:20	202:3	112:16 113:5	99:19 101:4
11:25:22 104:20	12:52:05 112:1	14 4:11 6:24	114:23 118:8	142:1 215:1
11:25:31 104:25	12:52:11 112:5	104:13,22 212:5	120:1	218:4,7 224:21
11:25:35 105:1	12:52:24 112:10	212:9	1997 54:15 121:1	2006 1:22 2:17 8:1
11:25:48 105:5	12:52:35 112:15	15 6:25 31:4 57:3,6	198:3,25 199:3	8:4 275:20
11:25:59 105:10	12:52:46 112:20	57:7 129:6 131:4	1998 18:2 63:8	201 6:23
11:26:07 105:15	12:53:05 112:25	210:16 219:14,17	230:14	21 7:7 229:14
11:26:14 105:20	12:53:09 113:1	152 6:15	1999 4:9,12,18	230:9
11:26:29 105:25	12:53:22 113:5	15209 8:7	11:20 23:18	212 6:24
11:26:31 106:1	12:53:35 113:10	15219 8:9	123:19 124:12	219 6:25
11:26:43 106:5	12:53:46 113:15	15260 3:14	231:7	22 51:18 52:5,7
11:27:01 106:10	12:54:05 113:20	155 6:16	<hr/>	92:2 231:7
11:27:24 106:20	12:54:20 113:25	157 6:17	2	226 7:1
11:28:37 106:25	114:1,5	1579 116:7	2 6:11 67:1 92:11	229 7:2,4,6,7
107:1	12:54:31 114:10	1580 121:23	110:1 122:20,22	23 4:17
11:28:50 107:5	12:54:48 114:15	16 7:1 215:1	154:22 157:5	230 7:3
11:29:18 107:10	12:54:58 114:20	217:24,25 218:1	163:6 165:21	24 56:18 63:8
11:29:26 107:15	12:55:07 114:25	226:8,12	166:6,11 185:2	222:19
11:29:39 107:20	12:55:13 115:1	169 227:2	193:22 194:15,25	25 104:24 107:15
11:29:52 107:25	12:55:14 115:5	17 4:14 7:2 164:25	213:3 223:22	129:19 131:5
108:1	12:55:24 115:10	229:13,17,19,21	225:12 243:8	198:10
11:29:59 108:5	12:55:26 115:15	230:8,12,13	2-11-99 7:4	27 216:7
11:30 106:19	12:55:39 115:20	17-Item 151:7	2/04/04 5:19	270 4:5
11:30:11 108:10	12:55:46 115:25	170 227:3	2/4/04 5:17	288-3376 1:24
11:30:16 108:15	12:55:52 116:1	1710 3:13	2:57 201:14	

3

3 6:12 77:24 92:8
 92:15 110:1
 122:22 150:14
 157:5 222:13
 223:22 269:2
3,4 122:20
3-16-04 5:21
3-30-99 7:7
3:04 201:18
30 4:19 70:19
 99:19 103:11
 206:19 209:6
 210:20 211:2,6
 211:12,19 212:3
 219:25 222:24
 224:17 266:7
 274:3
30309 3:9
32 4:21
329 6:20 7:2,6
 12:22 13:13 21:3
 63:11 65:11 70:7
 70:14 76:12
 77:16,23 82:4,8
 83:1,8,22 89:22
 92:18 95:4 96:10
 96:12 103:1,9
 110:10 120:19,22
 121:6 144:15,21
 144:23,24 145:12
 146:21 147:3,11
 149:7,17 150:16
 150:23 151:22
 152:14,19 155:12
 155:21 156:15
 157:22 158:19
 160:14,21 162:20
 170:7,24 171:13
 174:12 175:4
 177:12 178:7,13
 179:20 181:23
 182:12 184:15
 185:22 190:6
 191:4,8,16
 193:17 194:12
 198:5,25 199:17
 199:22 204:14
 206:9,11,25

207:3,19,22
 208:11,22 213:9
 213:16 222:8
 226:21,25 228:18
 236:10,15,24
 237:5,10,17
 238:6,12,15
 239:4,10,12,20
 239:22 240:5,8
 241:3 242:22
 244:2 254:23
 271:2,5,15

33 205:23
337 25:24
34 4:23
35 5:1
3543 19:23
36 222:13
377 26:2,8 38:8
 206:25 207:20
 220:18 221:5,6
 221:10,16,22
 222:2

38 218:10

4

4 6:13 47:9,10,12
 47:18 48:2 82:8
 84:20 85:9 107:4
 122:22 158:15
 201:15 223:22
4-14-99 232:5,14
4-16-04 217:21
4-24-99 232:6
4:00 240:18
4:09 240:23
4:28 274:24
4:41 268:14
4:43 268:17
4:48 274:23
41 4:8 11:14,17
42 4:11 14:16 23:8
 123:10,16 124:9
43 4:14 17:18,22
 23:8
44 4:16 18:25 19:1
 23:8 30:1
45 4:17 23:9,11,14
 212:20
46 4:19 30:3,4

47 4:21 32:12,13
48 4:23 34:20
49 5:1 35:23 39:17

5

5 1:22 2:17 5:25
 6:14 7:3 8:1,4
 90:18 129:11
 142:1 152:24
 153:1,7,11 154:5
 201:19 209:22
 223:22
5.9 86:24 87:2,6
 89:4,11,15,19
50 5:3 13:19 51:12
 51:15,19 63:1,5,6
 154:2,20 157:1
 159:1 247:5
 264:23
51 5:3,4 62:7
511 218:11
52 5:5 63:13,18
53 5:8 68:5,9 69:4
 72:19 74:4
54 5:9 68:22 76:9
 77:13
55 5:11 68:23
55.2 159:3
56 5:13 68:23 75:4
57 5:15 68:23 69:4
 74:11
58 5:17 80:10,14
 80:16 81:8 85:3
59 5:19 81:2,6,8,21
 81:23,23,25

6

6 6:15 83:11 90:23
 90:23 91:13
 142:6 152:25
 153:7,11 154:23
 183:12 223:22
 240:21 241:5
 246:24 247:1
6-10-04 5:13
6-13-04 75:12
6-9-04 5:15
6/13/04 5:8,9,11
60 5:21 13:19
 43:13 88:9

122:17 141:24
 151:13 214:9
 217:8
600 2:15,15
61 5:22 90:10,16
 141:25
62 5:4,24 99:7,8,18
 99:21 100:15,16
 242:5
63 5:5,25 99:21,25
 100:6,8 103:23
 103:24
64 6:1 103:14
 104:2
65 106:14,17 242:7
 242:9,12
65A 6:2
65B-1/4/06 6:4
66 6:5 260:1,4,24
66.7 159:2
660 8:8
68 5:8,9,11,13,15

7

7 6:16 90:19 92:1
 107:16 155:3,5,9
 241:5,9,10,12
7th 275:20
7-27-02 6:21
70 128:21 257:5,21
701 36:9 38:15,19
 39:6 207:1,20
 222:10,16,17
 223:4,11,15
 224:16,20,25
 227:15 245:14,17
 245:22
702's 38:24
74 51:18 52:5,7
764 154:12
765 247:19
766 170:22
769 199:20,23

8

8 6:17 13:22 154:2
 154:19 156:24
 157:1,17 159:1
 163:2 165:10
 177:22,25 188:20

242:20 243:9
 247:4 249:13
8.24 159:12
80 5:17 151:14
800 1:24
81 5:19
85 206:14
87 207:13
88 5:21

9

9 4:4 6:18 159:10
 165:1 168:21,24
 182:4,8 183:24
9-item 157:6
9-11-98 261:10
9.88 159:13
9/11/98 6:5
9:14 2:16 8:2,4
9:25 17:14,17
9:57 49:15
90 5:22
90025 3:5
950 3:5
98 56:18
99 5:24 15:2,8
99,line 5:25