

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

3 - - -

4 IN RE: TYLENOL : 2:13-md-02436-LS
(ACETAMINOPHEN) MARKETING, : PHILADELPHIA, PA
5 SALES PRACTICES AND :
PRODUCTS LIABILITY : April 27, 2016
6 LITIGATION : 10:11 a.m.

7 TRANSCRIPT OF IN-PERSON AND TELEPHONE STATUS CONFERENCE
8 BEFORE THE HONORABLE LAWRENCE F. STENGEL
9 UNITED STATES DISTRICT JUDGE

9 APPEARANCES:

10 For the Plaintiffs: LAURENCE S. BERMAN, ESQUIRE
THE LAW OFFICES OF LEVIN,
11 FISHBEIN, SEDRAN & BERMAN
510 Walnut Street, Suite 500
12 Philadelphia, PA 19106
(215) 592-1500

13
14 R. CLAY MILLING, ESQUIRE
HENRY, SPIEGEL, MILLING, LLP
Suite 2450
15 950 East Paces Ferry Road, NE
Atlanta, GA 30326
16 (404) 832-8000

17 CHRISTOPHER V. TISI, ESQUIRE
ASHCRAFT & GEREL, LLP
18 1825 K Street, NW, Suite 700
Washington, D.C. 20006
19 (202) 783-6400

20
21 (Proceedings recorded by electronic sound recording,
22 transcript produced by transcription service.)

23 VERITEXT NATIONAL COURT REPORTING COMPANY
MID-ATLANTIC REGION
24 1801 Market Street - Suite 1800
Philadelphia, PA 19103
25 (888) 777-6690

1 APPEARANCES (continued):

2 For the Defendants: DAVID M. COHEN, ESQUIRE
3 BUTLER SNOW, LLP
4 1700 Broadway
5 New York, NY 10019
6 (646) 606-2995

7 ALYSON B. JONES, ESQUIRE
8 BUTLER SNOW, LLP
9 Suite 1400
10 Renaissance at Colony Park
11 Ridgeland, MS 39158
12 (601) 985-4427

13 AUDIO OPERATOR: LAURA BUENZLE

14 TRANSCRIBER: JUDI Y. OLSEN, RPR

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

I N D E X

PAGE

COLLOQUY

4

ARGUMENT:

By Mr. Cohen

12, 96

By Mr. Tisi

52, 99

E X H I B I T S

NUMBER

DESCRIPTION

MARKED

ADMITTED

(None marked.)

1 - - -

2 THE COURT: And we have a rather limited
3 but packed agenda. I think the main event here is
4 the discussion of the supplemental reports, and so
5 we'll get to that very shortly.

6 In terms of where we are in New Jersey,
7 Mr. Berman?

8 MR. BERMAN: Yes, Your Honor. Laurence
9 Berman for the plaintiffs. I'd like to address two
10 points first, if I may.

11 With respect to the New Jersey report,
12 Mr. Milling will actually give you a supplement
13 today, as there was a conference call with Judge
14 Johnson yesterday. I was not available to
15 participate in that, so he will be able to give you
16 more up-to-date information about the New Jersey
17 on-goings.

18 THE COURT: Okay.

19 MR. BERMAN: The second point I wanted
20 to make -- and I'm not quite sure how -- how to make
21 it -- is that the plaintiffs were a bit surprised
22 about the audio/visual demonstrative display that was
23 set up for today's presentation.

24 THE COURT: I didn't do it.

25 MR. BERMAN: Well, I -- we were not

1 given any notice about that.

2 THE COURT: Right.

3 MR. BERMAN: And, certainly, if we had
4 known that that was the intent of the defendants, we
5 may have chosen to make our presentations in a
6 different format or a different manner.

7 THE COURT: There's no extra credit for
8 PowerPoint (indiscernible).

9 MR. BERMAN: And we actually have no
10 idea what is going to be displayed. We --

11 THE COURT: Right.

12 MR. BERMAN: Your Honor's standing order
13 has always been, provide courtesy copies of exhibits,
14 which we're prepared to do, for hand-up and so that
15 the court can follow.

16 We -- we don't know if this is cuts of
17 depositions, whether there's video. It's a complete
18 surprise, Your Honor, and we just feel that we were
19 entitled to notice and that, you know, perhaps we can
20 reserve an objection to the manner of presentation
21 that the defendants choose to make.

22 MR. MILLING: Good morning, Your Honor.

23 THE COURT: Mr. Milling, good morning.

24 MR. MILLING: Clay Milling for the
25 plaintiff.

1 As Your Honor, I think, is aware, the
2 parties are going full bore on multiple issues right
3 now as it relates to the Taylor (ph) case, which is
4 set for trial in late May.

5 We are -- have been working with the
6 defense on deposition designations because the
7 Taylor (ph) case involves two claims; failure to warn
8 is where the Jackson -- and -- and design defect,
9 while the case last year was just one claim. We're
10 lining up the deposition of treaters.

11 We are -- have jury questionnaire due on
12 the 9th, evidence list due on the 16th. So we're
13 going as fast as we can on that.

14 At the same time, the defendants'
15 motion, as it relates to the Acute Liver Failure
16 Group, has stretched everyone thin, with depositions
17 all over the country last week, from the East Coast
18 to the state of Washington.

19 Briefing on the Acute Liver Failure
20 Study Group issue in New Jersey, Your Honor, is due
21 on May 9th, with only a seven-day reply -- reply
22 period, and the parties are to be in New Jersey
23 beginning on May 16th for day-to-day arguments on
24 pretrials -- issues continuing until they're
25 completed; jury selection to begin May 23rd.

1 As Mr. Berman mentioned, there was a
2 call yesterday, a conference call, with Judge --
3 slash hearing with Judge Johnson. He wanted an
4 update on our ability to -- to meet the deadlines in
5 the scheduling order.

6 And then we had considerable discussion
7 about the Acute Liver Failure Study Group. He is
8 aware that Your Honor is hearing argument today. He
9 asked when we thought you would rule, to which we
10 said we did not know, but that the plaintiffs had
11 asked for expedited hearing and ruling.

12 And he was asked whether he would like a
13 copy of the transcript from today, and he said he
14 would, and he asked us if we could somehow work with
15 the court reporter to get a thumb drive so that we
16 can deliver a transcript of today's hearing to Judge
17 Johnson for his read.

18 He is currently reading the lead
19 deposition, the plan deposition, the (indiscernible)
20 deposition, trying to get his hands on the issue, but
21 he has not seen the motions and, again, would like
22 the benefit of the oral argument today.

23 So we're going in a lot of different
24 directions as fast as we can. Thank you, sir.

25 THE COURT: Okay. Thank you,

1 Mr. Milling. We should be able to accommodate the
2 request for an expedited transcript. I'll have to
3 look into the thumb drive request.

4 INDISCERNIBLE SPEAKER: (Indiscernible.)

5 THE COURT: Okay. All right.

6 MR. MILLING: And Judge Johnson's pretty
7 technologically savvy, so I -- I think just a quick
8 call and figure out how -- how we can get it over
9 there, no worries.

10 THE COURT: All right. We can do that.

11 All right. From the defendants'
12 perspective, Ms. Jones?

13 MS. JONES: Yes, Your Honor.

14 THE COURT: Good morning.

15 MS. JONES: Good morning. Ms. Jones.

16 The -- the -- I do not have anything --
17 additional comment. I think that Mr. Milling
18 accurately reflected what's been going on in
19 New Jersey.

20 There has been a significant amount of
21 information or documents transferred between both
22 courts, and so I want to -- we want to be sure that
23 we give Your Honor what he wants as well as what
24 we're doing in New Jersey as well.

25 So, for example, the -- Judge Johnson

1 does have copies of all of the briefing that's been
2 made in this court in the MDL.

3 One of the things that Judge Johnson has
4 been provided that the plaintiffs have actually been
5 providing to him in realtime are transcripts of all
6 the depositions as they've been taken.

7 So we -- we have copies of those, to the
8 extent that Your Honor would want those or want to be
9 furnished those. And so I just want to make sure
10 that all of the information is being shared to the
11 extent the court wants it.

12 THE COURT: Okay.

13 MR. MILLING: Lastly, just in terms of
14 coordination, Judge Johnson was -- has also been
15 provided Your Honor's rulings on motions in limine.
16 (Indiscernible) were helpful.

17 And so we -- as Alyson mentioned, we are
18 trying to keep both Your Honor and Judge Johnson in
19 the loop, given where everything seems to be with the
20 litigation generally.

21 THE COURT: All right.

22 MR. BERMAN: I just want to add, Your
23 Honor, you were previously provided with Judge
24 Johnson's scheduling order. I think it was the order
25 that was dated January 29th. And that's the order

1 that provided that the Kemp motions, which is similar
2 to Daubert, would not be filed until the depositions
3 were completed. So what he has been provided with
4 has been the courtesy copies of the filings in this
5 court.

6 THE COURT: Okay. Thank you.

7 MR. BERMAN: Thank you.

8 - - -

9 (Pause)

10 - - -

11 THE COURT: Okay. Why don't we talk
12 about the supplemental reports. Who's going to argue
13 that for the defendant?

14 MS. JONES: Yes, Your Honor. David
15 Cohen from our office is going to argue on behalf of
16 the defendants.

17 THE COURT: And are you responsible for
18 all this equipment, Mr. Cohen?

19 MR. COHEN: I am the guilty party, Your
20 Honor.

21 THE COURT: Okay.

22 MR. COHEN: Guilty -- we -- we had
23 presented an argument to Judge Johnson in September
24 on the Kemp motion, and we used audio/visual, and
25 there was no objection at that time.

1 THE COURT: Okay.

2 MR. COHEN: We did not, for this
3 purpose, Your Honor, use any video because of the
4 time frame involved from the depositions. So the
5 purpose of the -- of the visual -- we haven't used --
6 we're not using videotapes. The purpose of the
7 presentation of the visual was to, essentially, be
8 more efficient since there has been such a mountain
9 of evidence that has been produced in such a short
10 period of time and we have a short period of time
11 today to argue. So if I may?

12 THE COURT: Thank you. Now, in terms of
13 our schedule, I have a sentencing that was scheduled
14 at 2:00. I have a -- a commitment at 12:30. So
15 we'll -- we'll take about an hour on each side to --
16 to get this done.

17 Mr. Tisi?

18 MR. TISI: Judge, may I approach the
19 bench with -- with -- with Ms. -- with Ms. Jones for
20 a moment?

21 THE COURT: Sure.

22 - - -

23 (Whereupon, a sidebar conference was had
24 between 10:19 a.m. and 10:21 a.m.)

25 - - -

1 THE COURT: All right. Mr. Cohen.

2 MR. COHEN: Thank you, Your Honor.

3 The 19 so-called low-dose cases
4 published by the Acute Liver Failure Study Group in
5 the Larson 2005 paper, in our view, cannot reliably
6 support an opinion -- an expert opinion that 4 grams
7 or less of acetaminophen per day causes acute liver
8 failure.

9 I'd first like to start by posing a few
10 questions and trying then to answer them with
11 reference to actual documents in evidence, which I
12 hope will assist this court in making an assessment
13 of the underlying reliability of this evidence as
14 part of its gatekeeping role under Federal Rule of
15 Evidence 702 and Daubert.

16 The questions I would like to pose are
17 as follows:

18 First, what is the design of the ALFSG
19 Larson 2005 paper, and can it be used to establish
20 causation?

21 Second, what is the methodology that was
22 used to identify the low-dose cases in Larson 2005?

23 And, third, are there flaws in the
24 methodology that make the low-dose data unreliable
25 evidence of causation?

1 The plaintiffs' reliance, as the court
2 is aware, of this evidence is part and parcel of
3 their core medical causation theory in this MDL;
4 namely, that recommended doses of acetaminophen
5 caused plaintiffs' liver injury or liver failure.

6 And to prove this theory, the plaintiffs
7 and their experts rely upon a single paragraph in the
8 Larson paper, which is here. This is the abstract,
9 which is that. And this single paragraph is the
10 quote, unquote, low dose.

11 And when we refer to "low dose" today,
12 Your Honor, I'm referring to the way in which the
13 ALFSG in the paper defined "low dose," which is at or
14 under 4 grams of acetaminophen per day.

15 At the Jackson trial that we had in
16 New Jersey in September and October of this past
17 year, the plaintiffs' principal hepatologist,
18 Dr. Kaplowitz, testified to this data, and virtually
19 all of the plaintiff experts cite the Larson 2005
20 paper and the low-dose cases in their reports.

21 Dr. Davern, one of their experts, is a
22 coauthor of the paper, and he testified at his MDL
23 deposition that these 19 cases establish causation.

24 And, finally, as Your Honor may recall,
25 there has been much reference made by plaintiffs to

1 the FDA Working Group report on acetaminophen, and
2 that report also references the Larson 2005 paper and
3 the 19 low-dose cases.

4 This litigation sinks or swims on the
5 claim that 4 grams or less of acetaminophen causes
6 acute liver failure. That, in turn, relies on the
7 plaintiff expert opinion testimony on causation,
8 which, in turn, relies on the evidence in these 19
9 cases.

10 Plaintiffs' experts cite this article
11 because it is the only study of acute liver failure
12 that reports low doses of acetaminophen ingestion and
13 ALF. They cite to it because it was published by the
14 ALFSG, which they describe as, and their experts
15 testify as, the most important study of acute liver
16 failure in the United States.

17 I'd like to make some preliminary
18 observations, if I can get this right, before we talk
19 about the study --

20 Excuse me.

21 Thank you.

22 -- about the context.

23 In 2005, when the study was published,
24 there were 28 billion doses of acetaminophen
25 purchased by U.S. consumers. 28 billion with a B.

1 8 billion of those were single ingredient
2 over-the-counter acetaminophen products. And that's
3 from the FDA advisory committee.

4 Second, Larson 2005 low-dose cases
5 essentially stand alone. No other group of
6 researchers anywhere in the world have claimed to
7 have discovered this many cases of ALF attributed to
8 this dose of acetaminophen ingestion.

9 And, third, since 2005, since that one
10 paragraph was published in Larson, the ALFSG has not
11 published any follow-up studies on these cases. It
12 bears reminder that the study itself, the paragraph,
13 does not discuss specific cases. It does not discuss
14 how the ALFSG identified and evaluated those cases,
15 and since 2005, there has been no information
16 forthcoming from the ALFSG on these 19 cases. McNeil
17 asked for information but was rebuffed.

18 Now, the first question I'd like to
19 address is, what is the ALFSG, and is it capable of
20 establishing that low-dose acetaminophen ingestion
21 causes ALF?

22 The ALFSG is comprised of a collection
23 of cases that were collected on case report forms.
24 We're going to talk a lot today about case report
25 forms or CRFs.

1 Here is how Dr. Larson, the lead author
2 of the paper, when asked by plaintiffs' counsel how
3 she got the data, responded: The data was collected
4 on paper case report forms that we had identified
5 specific things we wanted to track.

6 So yes, the ALFSG is a series of case
7 reports, and they are reported -- and they are
8 described in the ALFSG protocol, known as the Manual
9 of Operations, as case report forms.

10 We will actually look at one of those
11 forms in a little bit, but the point I want to make
12 here preliminarily is that the -- is that the ALFSG
13 uses the term "case report" to describe its own data.

14 Now, Dr. Larson confirmed this, to
15 confirm the design of the ALFSG, at her deposition,
16 and -- where she said -- and then there are things
17 called case series, which are, say, a collection of
18 case reports? And she said, yes, correct. And the
19 ALFSG, as a registry, is, essentially, a series of
20 cases? Correct.

21 Dr. Larson then confirmed that the ALFSG
22 does not have a control group. Correct. She said,
23 it's not designed as a controlled study. And then
24 she was asked whether it's ever published risk
25 ratios. Those would be such as odds ratios or

1 relative risks. And she agreed. That's correct; we
2 are not designed to do that, was her testimony.

3 The ALFSG, therefore, as Dr. Larson
4 testified at her deposition, was not designed to
5 answer the question of whether acetaminophen
6 ingestion of 4 grams per day in divided doses causes
7 ALF.

8 So the ALFSG, therefore, is not a
9 clinical trial. It is not an analytical
10 epidemiological study with a control group. It is
11 simply a collection of case reports, known as a case
12 series.

13 So let's turn to the -- specifically to
14 the Larson 2005 paper. This paper was not designed
15 specifically by the ALFSG also to answer the question
16 of whether low doses causes ALF. Dr. Lee conceded
17 that.

18 Question: And can we agree that
19 Dr. Larson -- that Larson 2005 was not designed to
20 answer the question of whether acetaminophen
21 ingestion of 4 grams per day in divided doses causes
22 ALF? Dr. Lee responded, that's correct.

23 Dr. Larson said exactly the same thing,
24 a little bit differently, but let's go through it.

25 And in that protocol, you have in it, in

1 front of you -- there is not a single reference to
2 low-dose acetaminophen ingestion, is there?

3 And that's the Manual of Operations.

4 Over objection, she answered, that was
5 not the design of the study.

6 Dr. Lee acknowledges that the paper does
7 not report a statistically significant association
8 between acute liver failure and acetaminophen
9 ingestion of 4 grams or less.

10 He was asked this specific question,
11 whether there were any risk ratios reporting
12 statistically significant association between ALF and
13 low dose ingestion, and he said, it's -- there is
14 none.

15 Before moving to the low-dose cases
16 themselves, I'd like to offer two observations about
17 why the design of the ALFSG is so important to the
18 question of causality presently before the court.

19 First, case reports and case series
20 cannot establish causal associations. That's a
21 well-accepted principle in science and medicine.

22 Second, if Drs. Lee and Larson
23 themselves believed that the case report data in the
24 ALFSG and, specifically, in Larson 2005 established a
25 causal relationship between low-dose ingestion of

1 acetaminophen and ALF, they would have said that.

2 Instead, let's look briefly at what they
3 published and have told the scientific community that
4 acetaminophen -- about acetaminophen ingestion up to
5 4 grams a day.

6 And I want to just preface this by
7 pointing out that the Larson paper, which was
8 published in 2005, is based upon data collected by
9 the ALFSG between 1998 and 2003. The article took
10 two years to write and to publish. So the period of
11 which they -- when they collected data is 1998 to
12 2003.

13 In 2003, Dr. Lee published this with one
14 of his colleagues, Dr. Schiodt, S-c-h-i-o-d-t. And
15 in this paper, he -- they -- these two authors wrote,
16 taken within recommended doses, maximum 4 grams per
17 day, acetaminophen is a safe drug.

18 We asked Dr. Lee about that statement at
19 his deposition, and we asked, does it say that? It
20 does. Is that what you wrote 13 years ago? Yes.
21 You stand by that in general? Yes, we all know that
22 it's a safe drug in general.

23 We asked him again, do you stand by the
24 article? I would think it represents our thinking in
25 2003, yes. And you haven't withdrawn it? No, it's a

1 book chapter.

2 Actually, it's a series that comes out
3 either on a monthly or quarterly basis, and so it can
4 be, of course, annotated and updated.

5 Dr. Larson also wrote in 2007 an article
6 on acetaminophen hepatotoxicity. Now, this is, of
7 course, two years after Larson was published --
8 Larson 2005 was published.

9 And in that article, she wrote,
10 acetaminophen is effective and safe when consumed as
11 recommended, 1 to 4 grams per day.

12 We asked Dr. Larson about that. Did you
13 write that? I did. Do you stand by that? I do,
14 with some caveats -- which we're going to come back
15 to. And since this article has been published,
16 Dr. Larson, have you withdrawn that statement in any
17 articles you've published since then? No. And is
18 this article written two years after you -- you
19 published your 2005 paper? Yes. So at the time, you
20 knew about the 19 cases of low-dose ingestion? And
21 she said, yes.

22 Now, Your Honor, in 2009, Dr. Lee was
23 invited to the FDA to testify before the advisory
24 committee on acetaminophen. He was asked many
25 questions about that during his deposition by

1 plaintiffs' counsel.

2 But he was also asked at that testimony
3 at the FDA the following question: Is there a
4 point -- this is a question to Dr. Lee at the FDA
5 advisory committee. Is there a point where you would
6 opine that acetaminophen is a safe drug or that you
7 think would be a reasonable, safe dose for people to
8 take? And Dr. Lee responded, I guess I'd rather not
9 be pinned down; that's a tough one.

10 Now, we asked Dr. Lee about that. Is
11 that what you told the FDA? He said, it looks like
12 it.

13 Now, in 2013, Dr. Lee made a
14 presentation at the American Association for the
15 Study of Liver Disease, known as the AASLD. We've
16 heard a lot about it. They had an annual meeting, as
17 they always do. He was invited, and he even was
18 invited to give a presentation in honor of Hy
19 Zimmerman, known as the Zimmerman presentation.

20 And during his presentation, he -- he
21 elected -- I should preface this. He elected to
22 focus his presentation on acetaminophen. And he
23 showed a slide, number 21, and at the end of his
24 presentation -- and his presentation was virtually
25 all on overdose and the problem of overdose and how

1 to stop overdoses of acetaminophen causing liver
2 injury, which everybody acknowledges happens.

3 But he said at the end in his slide on
4 controversies remaining, low-dose ingestions,
5 question mark, as a controversy remaining.

6 So we asked him about this at his
7 deposition. And so you see there, so you wrote in
8 the second bullet point, low-dose ingestions,
9 question mark? Right, right. Why did you write it
10 as a controversy? And this is what he said, because
11 it's still uncertain; as you -- we just discussed a
12 moment ago, that these -- that we -- we haven't been
13 able to prove these completely, but there's certainly
14 evidence in favor of them existing.

15 And he went on -- I'm not
16 Mr. Finlay (ph). Well, what is a controversy in
17 medicine, we asked him. It means that people
18 disagree; they have friendly disagreements. And
19 there's nothing wrong with that, right? That's
20 right. For physicians and scientists to disagree
21 about science? And his answer was, there's
22 uncertainty.

23 Since collecting the 19 low-dose cases
24 between 1998 and 2003, this is what Drs. Lee and
25 Larson have said and published to the medical

1 community.

2 And I submit that if the methodology
3 used by the ALFSG to identify these 19 cases in a
4 paragraph in Larson 2005 were reliable and
5 convincing, I don't know how Dr. Lee could have
6 published in 2003 an article stating that 4 grams are
7 safe.

8 I don't know how Dr. Larson could have
9 published two years later, in -- after the article
10 was published, in 2007, that 4 grams are safe.

11 I don't know how Dr. Lee would have been
12 able to tell the advisory committee in 2009, when
13 asked about a safe dose, that he'd rather not be
14 pinned down.

15 And I don't know how Dr. Lee would have
16 told the annual meeting of the AASLD in 2013 that
17 this is still a controversy, a remaining controversy.

18 Dr. Lee certainly would not have
19 explained his prior writings and statements in this
20 proceeding as he did, using the words that -- we
21 haven't been able to prove these, and there is
22 uncertainty.

23 Where there is a lack of proof and a
24 lack of certainty, I submit that there cannot be
25 scientific reliability about causation.

1 I'd now like to turn to the second
2 question of the methodology of the ALFSG and,
3 specifically, Larson 2005. And so, as I mentioned a
4 moment ago, we're going to look at a case report form
5 to understand what went wrong.

6 These are the case report forms. This
7 is page 1. They're used -- they were designed by the
8 ALFSG. They're designed to enroll patients by the
9 different study sites into the registry. And
10 there's -- reminder, that these do not become part of
11 the patient chart.

12 - - -

13 (Phone ringing.)

14 - - -

15 INDISCERNIBLE SPEAKER: I'm sorry. I
16 thought it was off.

17 MR. COHEN: After the CRFs are filled
18 out by the study coordinators or the study
19 investigators at the different sites, they were
20 then -- at the time the Larson paper was written,
21 they were faxed to UTSW in Dallas.

22 A physician reviewed the forms at UTSW.
23 The physician may have queried the sites for
24 additional or missing data or resolution of
25 ambiguities. That's what Dr. Lee said they did in

1 his declaration.

2 Once the query responses were returned,
3 if there were any, the data in the CRFs that are
4 filled out in these forms was then entered into a
5 computer database.

6 And it's important to recall what they
7 said about this. It was entered in a head-down data
8 entry, which I just now have learned means that
9 somebody types the data into the database, no
10 questions asked. It's -- as it comes in, it gets
11 just put into the database without any questions.

12 Now, the Manual of Operations that the
13 ALFSG and Dr. Lee created for the ALFSG emphasized
14 getting good data and being careful. Here's what he
15 wrote, as the saying goes, garbage in, garbage out;
16 the data is only as good in the way in which it is
17 collected. And at the end of this quote here, he
18 says, this is vital; nothing will sink this project
19 like poor data collection.

20 THE COURT: And who said this?

21 MR. COHEN: Dr. Lee in the -- in -- in
22 the Manual of Operations -- I can't say it was
23 Dr. Lee. The ALFSG Manual of Operations. And the
24 specific cite for that, Your Honor, is the First
25 Edition, 1997, page 12.

1 We can -- we have copies of everything
2 we can give you, by the way. At any moment you need
3 a hard copy, we have everything.

4 There are several key sections for the
5 court, I think, to understand that are relevant to
6 the question of the reliability of the acetaminophen
7 dosing histories in these 19 cases, so let me just
8 walk you through them very quickly.

9 Section 13 is the date of onset of
10 hepatic encephalopathy or coma. This is the -- this
11 is the -- they have four grades, one through four.
12 In order to be enrolled in the ALFSG, you had to have
13 hepatic encephalopathy, which means altered mental
14 status.

15 They also tracked risk factors, and one
16 that they tracked was ETOH, which is alcohol. Also
17 important.

18 Another thing in the case -- case report
19 form is a section called Medications. And here you
20 can see -- and I meant to highlight it, but I -- I
21 failed to do it -- that it's -- it's medications last
22 six months, including toxins, herbs, mushrooms, and
23 OTC meds. That's anything over the counter, even
24 vitamins.

25 And then, finally, in section 18,

1 relating to acetaminophen specifically, they called
2 this section Acetaminophen Overdose. It bears worth
3 noting that in the case report form, they never --
4 they never had a section about low dose. They
5 assumed it was going to be all overdose. And so they
6 called this section Acetaminophen Overdose and called
7 for additional information on that.

8 And then, finally, they had a section
9 called Tox Screens, which we'll talk about, and the
10 acetaminophen level. And that's the blood level of
11 acetaminophen in patients when they get to the
12 hospital.

13 And then the last thing here, which are
14 blank, of course, since this is a blank form, are --
15 they provided two comment sections on the two
16 different parts of the form.

17 Now, the focus of Larson 2005, as I
18 mentioned a moment ago, was on acetaminophen
19 overdose. Of the 275 patients in the paper, 256 were
20 overdoses. There's only that one paragraph that I
21 described and showed earlier on page 1368 that
22 describes these 19 cases.

23 Dr. Larson was the primary author, and
24 Dr. Lee verified that the paper was written from a
25 spreadsheet.

1 Dr. Larson confirmed that the paper
2 was -- was written from a spreadsheet and,
3 specifically, the 19 cases.

4 So -- and tell us, Dr. Larson, how did
5 it come about that these 19 cases were identified?

6 Answer: When we looked at this data, we noted that
7 there were several cases, 19 -- I think there were
8 actually a couple more -- that had reported taking
9 less than 4 grams --

10 And I've highlighted "reported" because
11 these were reported --

12 -- which was at the time considered the
13 therapeutic limit, and we just wanted to look at them
14 and see if they differed from the patients who had
15 taken more.

16 And then Dr. Larson said -- we -- we
17 followed up and said, well, you said, when we looked
18 at this data. And she responded, and looked at all
19 the doses that we had available; that's when we saw
20 that there was some cases that fell outside of over
21 the 4 grams.

22 In other words, she was looking at a
23 spreadsheet, and here, she -- she confirms that,
24 which was marked as Exhibit -- as an exhibit to the
25 deposition. And, in fact, that's what Dr. Lee

1 verified in his declaration of January 30, 2016.

2 So it's important to keep that in mind
3 because what happened was, she never looked at the
4 case report forms when she wrote the paper. They
5 were never even sent to her. And that she confirmed
6 at her deposition.

7 And as you said earlier today, you
8 didn't write the paper from the case report forms?
9 No, they were at the main site --

10 That was in Dallas. She was in
11 Washington, the state of Washington.

12 -- and questions went to Dr. Lee and
13 other authors at the site if I had questions in the
14 database.

15 And she also didn't have a protocol that
16 was designed to help her confirm the low doses in
17 these 19 cases. Quote, there was no protocol
18 specifically for those 19 cases, other than the --
19 the main protocol, which is the Manual of Operations,
20 which has nothing about low-dose cases.

21 And, in fact, she confirmed, in the
22 Manual of Operations, there is nothing about low-dose
23 acetaminophen ingestion. No protocol, no mention,
24 nothing. That's their protocol.

25 Dr. -- excuse me. Dr. Davern, who is a

1 plaintiffs' expert in this case, Your Honor, in the
2 MDL, is a coauthor on this paper. I'm going to
3 mention him very briefly.

4 He testified at his deposition that he
5 never saw the low-dose CRFs, never evaluated them,
6 did nothing to verify the doses, and did not discuss
7 the low-dose cases with any of the site
8 investigators, with Dr. Lee, or with Dr. Larson --
9 that's at his deposition, page 41, line 10 to 42,
10 line 2 -- that he did not see any written analyses of
11 these cases, these 19 cases, before they were
12 published. And he -- and that's at page 42, lines 3
13 to 21. And he was a coauthor, and he reviewed
14 drafts, as he testified, of the manuscript.

15 Now, the part of the CRFs that's most
16 relevant to whether a -- low-dose case information
17 relating to acetaminophen is, of course, the
18 acetaminophen information in the form.

19 And Dr. Lee testified that the
20 credibility of these 19 cases rises and falls on
21 these low -- on the dosing histories. Well, the
22 basis for the classification is the credibility of
23 the dosing history that's in the CRF, correct?
24 Answer, the question is correct as you phrased it.

25 Now, I'd like to turn to the third and

1 final question, which is, are these cases flawed as a
2 result of the methodology that was used to write this
3 paragraph in this paper?

4 And as a just quick background, in this
5 proceeding, Your Honor, over very strenuous
6 objections made by the plaintiffs and after almost
7 two years of litigation in Texas, we have discovered
8 evidence about cases that has never been disclosed
9 before, not to the FDA, not to the NIH, not to the
10 editors or peer reviewers of the Journal of
11 Hepatology, which published the article.

12 We have also now received testimony that
13 has never been heard by anyone in the scientific
14 community. Dr. Lee admits publically for the first
15 time that three of the 19 cases should be withdrawn
16 as low-dose cases.

17 Here is the first one. And what we've
18 done here is just X'd out the first two digits of the
19 CRF number so that we don't have to have anything
20 sealed, because UTSW requires that that information
21 not be disclosed without confidentiality -- due to
22 confidentiality.

23 So this is -- we're going to refer to
24 them as the last three numbers of the CRF number. So
25 this is 026. And I have a binder, which plaintiffs'

1 counsel actually prepared. If they don't mind, I'll
2 just hand it to the court. CRF 026 is at tab 19.
3 May I approach?

4 THE COURT: Sure.

5 MR. COHEN: Thank you.

6 THE COURT: Thank you.

7 MR. COHEN: And everything I'm going to
8 show you is on the screen, but I just wanted you to
9 have it.

10 And you can see here, in the Medications
11 and in the Acetaminophen Overdose section, what was
12 written in was, a handful, by the study
13 investigators, handful of Tylenol. Not, obviously, a
14 precise dose. Dr. Lee withdrew that case as a low-
15 dose case.

16 THE COURT: Well, 6 is still a pretty
17 low dose, isn't it?

18 MR. COHEN: It's 50 percent more than
19 the maximum therapeutic dose. Sure, it's not 10
20 grams, but it's not 4 grams, and the criteria for
21 that paragraph was 4 grams or less.

22 And I will also submit to Your Honor, we
23 can present evidence, not today, about that case,
24 which puts that 6-gram dose into substantial
25 question. But I did not prepare to do that today.

1 And the reason I didn't prepare to go into that case
2 in very great detail with Your -- with Your Honor is
3 because Dr. Lee has withdrawn that case from the
4 publication as a low-dose case.

5 Now, the second case he withdrew is 035,
6 and here are some of the relevant portions of it.
7 And that's because the study site investigators on
8 the CRF had written Macrobid in three different
9 places -- actually, four. There's a reference to
10 nitrofurantoin in the Medication section. That's the
11 same as Macrobid, so in four places.

12 And that is an antibacterial agent known
13 to cause liver injury and acute liver failure, but it
14 got in and was published as one of the 19. And Dr.
15 Lee has concluded that that case should be withdrawn.

16 THE COURT: And he did that, really, on
17 the basis of that adduct test, right, that was
18 conducted after the Larson paper?

19 MR. COHEN: He says that the adduct test
20 may have helped him understand more about these
21 cases.

22 THE COURT: All right.

23 MR. COHEN: But what he also testified
24 was that this had an alternative cause, which was in
25 the CRF, but was not used in 2005 as a basis to

1 exclude it.

2 THE COURT: All right.

3 MR. COHEN: It was ignored. And, of
4 course, as you know, they didn't have adducts in
5 2005.

6 THE COURT: All right.

7 MR. COHEN: And we'll talk about adducts
8 later.

9 So we're going to look at one more case.
10 I'm not going to go through the details yet of this
11 case. I will in a few minutes. But this case
12 involves a very unfortunate, tragic situation of a
13 35-year-old female, who was drinking substantial
14 quantities of alcohol, took a Tylenol overdose, as
15 written in the record, then took d-CON -- now, d-CON
16 is rat poison -- in a suicide attempt noted in the
17 CRF and died very tragically.

18 And she was -- a death note was sent to
19 the L.A. coroner's office by the medical institution,
20 signed by a doctor and a second person, indicating
21 she died of acetaminophen overdose.

22 And so when we presented all that to
23 Dr. Lee, when asked, well, given all that data,
24 classifying this case as somebody who simply took
25 acetaminophen as directed, he said, I would have to

1 say no.

2 And so we got -- after these three cases
3 with Dr. Lee in his deposition, we asked this
4 question. This comes right after this d-CON case.
5 We call it the d-CON case, just to remind ourselves.
6 So you withdrew this from that classification,
7 correct? Question: So we've withdrawn three cases,
8 right? And his answer was, yes.

9 Now, Dr. Larson, the first author on the
10 paper and who wrote the paper, withdrew two cases
11 immediately. Dr. Larson attempted to defend the
12 d-CON case, case 042, which Dr. Lee had agreed to
13 withdraw. I will show you this testimony, because
14 it's an outstanding example of why this paper and
15 this discussion of 19 cases is methodologically
16 flawed.

17 Let's look at the case report form 042,
18 which is at tab 14 of your binder, but you can look
19 at it on the screen.

20 And here, you can see, in section 13,
21 that this patient came in with hepatitic coma -- so
22 she had altered mental status -- and proceeded very
23 quickly to a very serious state of -- where she
24 became comatose very quickly.

25 She was drinking 80 grams of alcohol a

1 day for an unknown period of years. 80 grams.

2 The medication list in this CRF for this
3 patient, Your Honor, is completely blank. There's
4 not a single acetaminophen product listed, not
5 Tylenol, not Lortab, not Vicodin, not generic
6 acetaminophen. We don't know the date last taken.
7 We don't know the total dose. We don't know
8 duration. Everything is completely blank in the CRF.

9 The only reference to her dose is in the
10 Overdose section, where somebody wrote in 1,200 --
11 1,200 milligrams. That's 1.2 grams. I'll get back
12 to that.

13 And the acetaminophen level, she had a
14 level of 120, and -- and -- and that number may not
15 have relevance in the abstract, but the typical
16 level -- depends on the -- on the institution -- is
17 anywhere -- for recommended dosing of acetaminophen,
18 the maximum level ranges from about 20 to 30. She
19 was at 120.

20 Her history was given by the father and
21 the investigator. The treating doctors, the study --
22 the study investigator for this site who enrolled
23 this patient, here's what they wrote: 35-year-old
24 female, Tylenol overdose and d-CON ingestion along
25 with heavy alcohol use several days prior to a

1 suicide attempt.

2 Dr. Larson --

3 Oh, last part. This is the coroner's
4 office record -- or the -- the note to the coroner's
5 office on a coroner's form from the county of
6 Los Angeles, where you can see acetaminophen overdose
7 written four times by the doctor and whoever else
8 submitted that form. Two people signed it.

9 So we asked Dr. Larson. First of all,
10 she said, well, I wasn't reviewing the CR -- the CRF.
11 She didn't review all that information we just saw.

12 So we asked her, okay, well, how do
13 you -- even though you aren't reviewing the
14 information -- she knew it was 1,200 milligrams
15 because she had a spreadsheet -- well, how do you
16 take 1,200 milligrams?

17 And -- and let me just explain that.
18 Tylenol or acetaminophen comes in 325- and
19 500-milligram doses. You can't multiply those in
20 whole tablets in any combination to get to 1,200.
21 We -- we tried. We did some simple math. It doesn't
22 work. You have to cut up pills to get to 1,200.

23 Somebody making a suicide attempt, where
24 the history is being recorded by the father, is
25 unlikely cutting up pills to commit suicide and get

1 to 1,200 milligrams of acetaminophen.

2 So she -- she admits it's an incorrect
3 dose.

4 And then, why -- I asked her, why would
5 the Tylenol overdose referenced in section -- why was
6 that specific reference, the reference we saw by the
7 treating doctor, never queried, the reference to
8 Tylenol overdose? I don't know, because the main
9 site was the location where all -- where -- where
10 these were all initially vetted. So you don't know
11 why this was not queried in 2002? No, I do not know.
12 Or in 2005 when you wrote the paper? No, I did not
13 have the case report forms.

14 And then, of course, she knew about the
15 fact that it says acetaminophen overdose in four
16 places in the -- in the report of the death to the
17 L.A. coroner's office. We asked her, do you have any
18 basis to dispute that? No.

19 And, finally, she said -- we asked her,
20 you would not present this case today based on the
21 CRF and the death? She said, it would have been more
22 carefully queried today than it was 14 years ago.
23 You're on the causality committee now, right? Yes.
24 And as a member of that causality committee --
25 answer, we would have queried it. And you would not

1 today categorize this case of a low-dose case of
2 acetaminophen causing ALF, correct? Answer: We
3 would have potentially have called it an unknown
4 dose.

5 Your Honor, this testimony from
6 Dr. Larson, I think, highlights and shows the flaws
7 in the methodology that was used to evaluate and
8 query or not query the acetaminophen dose information
9 in the CRFs.

10 Like Dr. Lee, Dr. Larson now believes
11 that at least three out of these 19 cannot be
12 classified as ALF from low-dose ingestion of
13 acetaminophen. That's almost 16 percent error rate.
14 That's an error rate unacceptable in any field of
15 science and, specifically, in medicine.

16 Let's look at one more CRF. Let me see.
17 Hang on, please.

18 - - -

19 (Pause)

20 - - -

21 MR. COHEN: And it's case 008, and it's
22 at tab 9. Now, Dr. Lee testified that the data in
23 the CRF for this case do not fulfill criteria for
24 assigning acetaminophen as the cause of the patient's
25 ALF.

1 "Criteria" means -- in the study, to be
2 assigned acetaminophen, you had to take either more
3 than 4 grams, you had to have an ALT over a thousand,
4 or you had to have some level of acetaminophen in
5 your blood when you came into the hospital. Those
6 were the attribution criteria for acetaminophen.

7 Matt, could you show us Lee 299? Do you
8 have that handy?

9 Dr. Lee explained that the study's
10 prespecified criteria for attributing acetaminophen
11 to that case were waived. Let's see if we can find
12 it.

13 And I'm sorry. It may not be here, so
14 I'm going to read it into the record. That's the
15 problem with technology.

16 Ah, here it is. Found it.

17 Dr. Lee testified --

18 INDISCERNIBLE SPEAKER: I think I
19 (indiscernible).

20 MR. COHEN: Oh, you're right.

21 THE COURT: Go back one.

22 MR. COHEN: Yeah, it keeps jumping on
23 me.

24 INDISCERNIBLE SPEAKER: Forward.

25 Forward. Forward.

1 MR. COHEN: Yeah, that's it.

2 So he said he waived it, he said. He
3 waived the criteria. So we said, who waived it?
4 That would have been me. Where is the waiver
5 discussed in the CRF? Oh, this was usually a
6 telephone call from the site. To who? To me, from
7 the site investigator to me. Is that telephone call
8 documented in any part of the CRF or any other
9 documentation you can provide to us today? This was
10 the first six months of the study being started in
11 1998. Well, how do you recall this was waived, given
12 the age of the case? Answer: Because that was a
13 common practice, I would say, in the beginning; if
14 they were -- if somebody had the data from the
15 previous hospitalization and it looked like a good
16 case, we were eager to get cases in those early days,
17 and we -- I might have accepted it even though the
18 labs didn't quite compute.

19 Frankly, Your Honor, I found this
20 testimony to be astonishing. It clearly shows bias
21 in methodology. A single person had a -- in an
22 unblinded fashion simply waived criteria for
23 assigning acetaminophen, didn't document his waiver,
24 and never informed the peer reviewers and the readers
25 of the Journal that this was, quote, a common

1 practice in the early days.

2 When a researcher admits that he's
3 collected data in violation of his own predetermined
4 criteria because he's eager to get cases and then
5 doesn't disclose it, I submit, Your Honor, that is
6 bias in research and bias in reporting.

7 But don't believe me on that. Here's
8 Patricia Robuck, who the plaintiffs also have
9 sponsored as a non-party witness. She was the
10 program officer at the NIH for the ALFSG, and she
11 testified about this very issue.

12 Are you aware, in the ALFSG study, if
13 scientists could unilaterally waive -- decide to
14 waive qualification requirements and admit a subject
15 or enrollee? Answer: No one is allowed to do that,
16 but no, they are not allowed themselves,
17 individually; that's what being part of a protocol is
18 all about; you must follow the protocol.

19 Now, Dr. Robuck told us that even if the
20 waiver in a study was performed, it must be
21 documented. Let's go back to the question of waiver.
22 If an individual scientist decided to waive some of
23 the qualifying criteria, any or all of the qualifying
24 criteria, you would expect that waiver to be
25 documented in the record, wouldn't you? Answer:

1 Yes. Question: And it's important that it be
2 documented, correct? Answer: Yes.

3 Dr. Robuck even said the NIH expects a
4 lack of bias in research and reporting and the NIH
5 also expects from its grant recipients, of which the
6 ALFSG is one -- it is true, a lack of bias in the
7 reporting? Answer: Yes. A lack of bias in the
8 researching? Yes.

9 Dr. Lee's waivers, which he testified he
10 never documented, which he did so commonly in the
11 early days to get cases, clearly do not conform to
12 Dr. Robuck's testimony on what the NIH expects from
13 its researchers.

14 Now, Dr. Larson was asked about this
15 same CRF, the one in which Dr. Lee unilaterally
16 waived criteria and didn't document. Now, because he
17 didn't document it, Dr. Larson didn't know about the
18 waiver. She didn't know. Therefore, unlike Dr. Lee,
19 Dr. Larson testified that although this patient was
20 properly in the ALFSG, because the patient had ALF,
21 the patient would not properly be included in the
22 paper.

23 And here's what she said. You have
24 study criteria for a reason? Yes. And if patients
25 don't meet those criteria, they should not be in the

1 study? As I said, this would be queried more
2 carefully -- today more carefully. Question: This
3 patient should not be in the study? Answer: This
4 patient is appropriate for the study; this patient
5 would not be included in the paper. In the paper?
6 Yes.

7 So -- so Dr. Larson has now conceded
8 that there are four cases where the -- of the
9 low-dose cases where the methodology was so flawed
10 that today she would say they don't belong in the
11 paper.

12 That is an error rate of over 21
13 percent. That's not acceptable in medicine or
14 science. No one -- no one wants his or her doctor to
15 practice medicine with a 21 percent error rate.

16 I have now shown you four cases that are
17 so obviously flawed that Dr. Lee, for three of them,
18 and Dr. Larson, for four of -- four of them, would
19 not today characterize them as low-dose cases.

20 And plaintiffs have made a lot about the
21 fact that the FDA and the NIH have reviewed and
22 approved the methodology of the ALFSG. It's all over
23 their papers and all over the declarations that were
24 written for these experts. Yet Dr. Lee tells us that
25 these CRFs were never provided to the FDA or to the

1 NIH, so these agencies had no reason to know about
2 this.

3 Okay. You never sent -- this is to
4 Dr. Lee. You never sent the CRFs for the 19 cases to
5 the FDA? Answer: Not that I'm aware, no. Question:
6 And you never sent them to the NIH? No.

7 Your Honor, there's a more grotesque
8 aberration of science we still need to discuss with
9 respect --

10 THE COURT: You're going to have to wrap
11 it up shortly.

12 MR. COHEN: -- to these cases.

13 I will.

14 In June 2009, Dr. Lee told the FDA
15 advisory committee that the ALFSG was going to
16 publish Larson 2. All right? And he said that.
17 Here's the statement from his testimony to the FDA.
18 You can see Larson 2. That's in June 2009, and
19 here's the slide that he showed; we plan a Larson 2
20 paper. Okay?

21 And, in fact, what we found was that
22 they actually started looking back at the Larson 2005
23 data in 2009 as part of something they called the
24 Data Clean Project. And that's an email that
25 describes -- or that conveys some spreadsheets to

1 Dr. Lee about Project Data Clean.

2 And it takes a little bit of me to
3 explain this to you, so bear with me, if you will,
4 and I'll do it as quickly as I can.

5 But Dr. Larson testified that the --
6 they wanted to make the data as clean as it could be,
7 presumably for Larson 2.

8 And here is the spreadsheet, 3 --
9 UTSMC30059. And it has colors, and one of the colors
10 is gray, and gray means excluded from the study for
11 some reason.

12 This is a medical student who's going
13 through the data at Dr. Lee's request and looking and
14 seeing, how is the data from Larson 2005?

15 And so what he concluded was that case
16 042, the d-CON case, should be excluded. It was in
17 gray. And he concluded that another case, 051,
18 should be excluded. It was in gray.

19 And he concluded in the green, a case,
20 116, should be re-categorized not as -- not excluded
21 from the ALFSG or the registry but re-categorized as
22 an overdose case because of a dosing -- a problem in
23 the dose -- the day -- the day of the -- the days of
24 dosing.

25 And then they put together this

1 spreadsheet, which is -- which has a column called
2 Delete on it. And here, you can see case 042,
3 (indiscernible) d-CON poisoning, in the Delete
4 column.

5 And we asked Dr. Larson, what does the
6 graying indicate in the spreadsheet, and that
7 spreadsheet has suggested this was excluded. And we
8 asked Dr. Larson, so according to the spreadsheet,
9 this was excluded?

10 And this is one of the other cases I
11 just talked about. I'm going to try to hurry this
12 along.

13 And she said, yes, it was excluded in
14 2009. And -- and -- and then we asked Dr. Larson
15 again what this all meant, and if you go back to this
16 spreadsheet, does it indicate that this was
17 reclassified from a low dose to an overdose? That's
18 the green case that I showed you, 116.

19 And she eventually said -- do you
20 remember this? I mean, I remember they were doing
21 it, yes, that they had re- -- reclassified that case
22 as an overdose.

23 And so we asked her, you were
24 reevaluating -- the ALFSG was reevaluating the Larson
25 2005 cases as part of the total second group? Yes, I

1 believe that's true. This is in 2009.

2 And then she said, so let's -- we then
3 go back to the 042 case, and she says, I'm asking
4 you -- or I asked you, I'm asking you, in 2009, you
5 and Dr. Lee and the ALFSG decided that it should be
6 deleted for Larson 2? And that she -- and she
7 answers, that would appear what this says.

8 And so, therefore, in 2009 -- this is
9 case 116. It falls out. That's the 116 case. I'm
10 just going to hurry this along.

11 So I asked her, don't you think it's
12 important information to the question of whether or
13 not these are reliable cases of low-dose ingestion at
14 4 grams per day or less, this Data Clean, this -- all
15 these spreadsheets showing this reevaluation? And
16 she admitted, yes, it's important.

17 But here's the point, Your Honor.
18 Dr. Larson doesn't mention Project Data Clean in her
19 declaration. Dr. Lee doesn't mention it in his
20 declaration. They don't mention that in 2009, they
21 went through this evaluation process and excluded
22 cases.

23 And here's how Dr. Larson described it.
24 So nobody ever learned that these low-dose cases had
25 been excluded by the ALFSG other than the ALFSG?

1 Answer: This just hasn't been done yet. Question:
2 In 2009, when the ALFSG decided to delete these two
3 cases, did you have any conversation with anybody at
4 the ALFSG about correcting Larson 2005? No. Did you
5 think about sending an errata or an explanation; hey,
6 the data has been reanalyzed, and we've excluded five
7 cases, and two of them were low-dose cases -- because
8 we went through three others that were not low dose.
9 No. And that's never been made public until today?

10 Answer: Well, yes, that's probably true. Never told
11 the FDA? No. Never told the NIH? No.

12 We didn't examine today every single CRF
13 with Dr. -- we didn't examine at their depositions
14 every single CRF with Dr. Lee and Dr. Larson. That
15 would have taken a couple of days. We didn't have a
16 couple of days. They're non-party witnesses. There
17 was a lot of resistance to us having time to depose
18 them, but we deposed them as best we could.

19 And what we now have learned is that we
20 already have, at a minimum, either 16, up to 21
21 percent of the -- of the cases being excluded based
22 upon the methods -- based upon the methods used to
23 publish these data.

24 And what is important about these flawed
25 data is exactly what Dr. Robuck has said. Can you

1 point to me any NIH document where NIH says, there's
2 certain amounts of data that we can accept as flawed?
3 No. Can you point me to any NIH protocol where they
4 say, eh, a little bit of data -- bad data is okay?
5 No. Can you point me to any -- any NIH protocol, any
6 NIH regulation, any federal regulation which supports
7 your statement and your testimony earlier that you
8 said a certain amount of data problems are okay; can
9 you point me to that? No.

10 And, finally, Dr. Lee wrote to a U.S.
11 senator in 2006 in connection with a clinical
12 research study involving a different drug, not
13 acetaminophen, which was believed to cause liver
14 injury. Dr. Lee wrote to the U.S. senator about the
15 company's sponsorship of that study.

16 The company is certainly to blame for a
17 faulty study, and no one should consider that any
18 flawed data in a study -- and one should consider
19 that any flawed data in a study throws out all that
20 data.

21 In conclusion, Your Honor, science
22 requires setting up a hypothesis, designing a study
23 to test it, and testing it. Acetaminophen causing
24 ALF at low doses was not the design of the ALFSG, and
25 it was not the design of Larson 2005, as both Dr. Lee

1 and Larson testified.

2 Where a study is not designed to answer
3 a question of causation, data pulled from that study
4 cannot be later used to answer that question. This
5 is not an analytical epidemiological study. That is
6 not what the ALFSG is all about.

7 But even if we accept that this is the
8 only valid way of examining acute liver failure and
9 low-dose acetaminophen, which we dispute, the methods
10 used here to collect and analyze the data with
11 respect to the dosing of acetaminophen in these 19
12 cases was obviously highly flawed.

13 We have seen now several examples that
14 even the lead principal investigator and the lead
15 author of the paper have testified that they would
16 not stand by those cases today as low-dose cases.

17 Dr. Lee's testimony in a short
18 deposition produced the astonishing admission of a
19 16 percent error rate, and Dr. Larson admitted to a
20 21 percent error rate.

21 The FDA didn't know about these cases.
22 The NIH didn't know. The readers of Hepatology
23 didn't know. The only people who know are us, and
24 sometimes flawed studies get past peer review, and
25 this is one example.

1 When Dr. Larson wrote in 2006, one
2 should consider that any flawed data in a study
3 throws out that data, he was right. That principle
4 applies here.

5 Your Honor, there are some additional
6 issues that I would like to reserve a few minutes of
7 time to discuss, if I may be permitted, after counsel
8 for plaintiffs presents.

9 THE COURT: Let's see how we are with
10 time.

11 MR. COHEN: Thank you.

12 THE COURT: Thank you.

13 Mr. Tisi.

14 MR. TISI: Judge, I'd like to, first
15 off, thank the court for agreeing to hear this on an
16 expedited basis. It's, obviously, important to the
17 parties as a practical matter for not only this trial
18 and the evidence that will come, that we have to
19 amass for a September trial, but it's also important,
20 as Mr. Milling pointed out, I think Judge Johnson is
21 looking, if I can be so bold, to some of the things
22 that we're doing here.

23 As I also indicated, we were taken
24 off -- a little bit off with the PowerPoint
25 presentation, but I'm going to do the best I can to

1 jump around.

2 I did prepare for Your Honor a binder,
3 as we -- as has been typically done in the past for
4 exhibits that we might refer you during the course
5 of -- of this argument. And with your permission, I
6 would --

7 THE COURT: Sure.

8 MR. TISI: -- like to hand it to you.

9 THE COURT: Alyssa (ph), you can take
10 it.

11 Thanks.

12 MR. TISI: The question that we have
13 before the court is -- is pretty straightforward;
14 does Daubert require the court to relitigate -- or
15 allow the court to relitigate, as defendants have
16 suggested the court do, the validity of a study like
17 this that has passed -- passed not only peer review
18 by the -- by the Journal of Hepatology but, as you
19 will hear, the National Institute of Health? And
20 this data has been presented to the -- to the FDA.

21 Specifically, you're going to be asked
22 whether or not we should wrap 11 cases or 17 cases
23 into the trial of this single case and whether or not
24 this is a -- ultimately, in the end of the day, a
25 collateral issue that doesn't go to the issues in the

1 case.

2 The answer to those questions, I would
3 submit, is no. The study is reliable for the
4 proposition for which it is being used and for which
5 it is being cited. That is three issues.

6 First, that there are, in fact, cases of
7 low-dose acetaminophen-induced acute liver failure.
8 Two, there is a narrow margin of safety for
9 acetaminophen. Three, that all of the cases in this
10 study, not just the 19, establish this margin of
11 safety, and the defendant has not challenged the rest
12 of the study.

13 Importantly, Mr. Cohen has indicated
14 that this is the only study out there that suggests
15 that there is a risk at low dose. Of course, this
16 court has been involved in this case for a long time
17 and knows that that is not true.

18 For example, the FDA scientists who have
19 looked at this question in the Working Group document
20 that Mr. Cohen referred to has indicated that the
21 Larson results reported in this paragraph are
22 identical to those reported by the FDA in its own
23 database.

24 So, for example, if I can point out to
25 you, in your binder, there is the FDA Working Group

1 document, which the court is familiar with but may
2 not have focused on this particular paragraph on
3 paragraph number -- on page number 11, where the FDA
4 Working Group --

5 And it's -- I have a copy if the
6 court --

7 THE COURT: Is that in this binder,
8 Mr. Tisi?

9 MR. TISI: It is in this binder. I
10 believe it's the fourth tab.

11 THE COURT: The one that says, Working
12 Group?

13 MR. TISI: Yes, correct.

14 THE COURT: What page?

15 MR. TISI: If you look at page 11 --
16 it's actually on page 10. It talks about the
17 recommendation that the dose be lowered to increase
18 the margin of safety --

19 THE COURT: Right.

20 MR. TISI: -- for acetaminophen. You --
21 do you see where I am, Your Honor?

22 THE COURT: I do.

23 MR. TISI: Okay. It says, although the
24 acetaminophen manufacturer asserts that the data do
25 not support the assertion that repeated

1 supratherapeutic ingestion of less than 10 grams a
2 day presents a risk of hepatic injury, the EHRs
3 database -- and that's an FDA database -- and the
4 database of the Acute Liver Failure Study Group show
5 that doses closer to 4 grams a day, the current
6 maximum dose, presents a dose -- a risk in some
7 individuals.

8 And if you look at the footnote, it
9 indicates the EHRs database and the F -- ALFSG
10 database shows the median daily dose of acetaminophen
11 was 5 to 7.5 grams a day. And that's the median.
12 That's the -- that's midpoint. So some below, and
13 some above.

14 If you go to the next page, go to -- the
15 FDA Working Group reiterates that point because
16 McNeil, again, said what Mr. Cohen said; the case
17 reports are unreliable evidence for the -- for
18 determining risk.

19 And the FDA Working Group says, the FDA
20 acknowledges the difficulty in defining a safe daily
21 dose relying on case reports; there are, however, two
22 different databases that suggest toxicity may occur
23 in some people with doses close to 4 grams a day.

24 So the FDA has indicated that this ALFSG
25 database is reliable because it has been replicated,

1 not only in their database, but elsewhere.

2 I would also point out that there are
3 clinical trial data that indicates that at 4 grams,
4 there is an elevated risk of -- of hepatotoxicity.

5 There are other individual cases,
6 including what the defendant has indicated is not, in
7 the medical literature and which you will see is
8 actually in this group of 19 cases, cases where
9 people were administered acetaminophen in a hospital
10 setting, in a -- in a situation in which the dose is
11 considered to be reliable because it's administered
12 by a doctor, and the person goes on to develop acute
13 liver failure.

14 So the first thing I would like to say
15 when we start out is that -- is that this evidence,
16 as important as it is, does not stand alone, as
17 Mr. Cohen suggests, but is, in fact, part of a
18 larger -- a larger spectrum of evidence, from animal
19 data to clinical trials to epidemiology observations
20 like this to case reports, that has convinced the
21 scientific and medical community, except for McNeil,
22 that there is a narrow therapeutic margin and a risk
23 at or near 4 grams.

24 Mr. -- before diving into my argument on
25 this, Mr. Cohen made several startling

1 characterizations of some of the witnesses in this
2 case. I would start with one to illustrate the point
3 and the point of using snippets, like Mr. Cohen used,
4 to illustrate here.

5 If you recall, when -- he indicated that
6 Dr. Lee had indicated that there -- this is a safe
7 drug and that there was no risk until you get to
8 close to 10 grams. There was a 2003 article on that.
9 There are multiple articles, from 2003 forward, where
10 Dr. Lee indicated there was a risk at 4 grams.

11 In fact, if you go to your binder -- I
12 didn't think I was going to have to do this, but if
13 you go to the binder, under the section -- there's a
14 section in which I collected testimony from the
15 various witnesses who have been -- testified in this
16 case on various issues.

17 And one is on the issue of the risk at
18 10 grams, and I asked Dr. Lee the following
19 questions. And it's on page 86 of his deposition.
20 Before I get to --

21 THE COURT: Where are you in the binder?

22 MR. TISI: It's on the page -- it's in
23 the binder on number 3, risk at less than 10 grams.

24 THE COURT: Right. Got it.

25 MR. TISI: And I pulled -- there are --

1 there is -- this was actually for another purpose
2 that I had this binder made, but there are snippets
3 from the various deposition --

4 THE COURT: Did you make this for me?

5 MR. TISI: I did. I did, but it was
6 a -- I didn't intend to use it, frankly. I intended
7 to use it, frankly, with -- in another context.

8 But there is -- there are pieces of
9 deposition testimony from the various witnesses in
10 this -- behind this binder. But if you go to the one
11 that deals with Dr. Lee, page 86, I asked him the
12 question at line 17: Before I get to discussing the
13 Larson paper specifically --

14 And my preface question was, I want to
15 talk about your public statements, the things you
16 have published in the past 10 to 15 years on
17 acetaminophen.

18 Before I get to discussing the Larson
19 paper specifically, let me ask you a global question;
20 in your 20-year work with the federally funded Acute
21 Liver Failure Study Group, have you developed and
22 reported an opinion in the medical literature that
23 some patients with acetaminophen- induced liver
24 failure can occur at 4 grams or less? Yes. Can it
25 occur at 5 grams? Yes. Can it occur at 6 grams?

1 Yes. And so forth.

2 And then I asked him the question, on
3 line 11, if anyone were to say that a human being
4 cannot develop acute liver failure until they get to
5 10 grams a day, is that something that would be
6 consistent with your experience running the largest
7 acute liver failure registry in the world? No.

8 Are these opinions that you, on behalf
9 of the Acute Liver Failure Study Group, reported to
10 the FDA in a public forum? Yes. And I go through
11 all the opportunities that he had to actually put
12 that out there.

13 So when Mr. Cohen puts out a 2003
14 chapter from a medical -- from -- that Dr. Lee wrote
15 and ignores the rest of his published literature for
16 the past 15 years, I think you ought to take note of
17 that.

18 Let me go -- let me take a big picture
19 here and back up a minute and see where we are and
20 why we're here a year and a half after we started
21 filing the various motions in this case discussing
22 the Acute Liver Failure Study Group.

23 As this court is aware, there are two
24 big picture questions that deal with the generic
25 issue, not only in the Taylor (ph) case -- excuse

1 me -- not only in the Hayes (ph) case, but in all of
2 the cases.

3 Number one, can acetaminophen cause
4 acute liver failure at or near 4 grams either above
5 that dose or below that dose?

6 Number two, should McNeil have had
7 knowledge of acetaminophen's narrow therapeutic
8 margin such that they should have taken risk
9 reduction measures in the early to mid-2000s,
10 including, among other things, lowering the dose,
11 giving better instructions, redesigning the product
12 to increase the margin of safety?

13 To answer these two important generic
14 questions at trial, the plaintiffs rely heavily not
15 only on the science but on the consensus of the
16 medical and scientific and regulatory community about
17 acetaminophen.

18 As both this court and Judge Johnson has
19 noted, it is -- it is the consensus of the medical
20 and scientific community and that McNeil stands
21 squarely outside of that consensus.

22 In fact, we quoted in our papers the
23 numerous times that Judge Johnson has said that there
24 appears to be a consensus in the medical and
25 scientific community; McNeil just wasn't part of it.

1 So that's the background, and so we have
2 to understand what it is that the defendant is trying
3 to do here, because the defendant is standing
4 squarely against the FDA, the FDA Working Group, the
5 Acute -- the American Association for the Study of
6 Liver Disease, the American Liver Foundation, the FDA
7 advisory committee votes, and the Acute Liver Failure
8 Study Group.

9 So what are they doing here, and why are
10 we doing this? Well, they're trying to undo the
11 decades of consensus. McNeil believes that if they
12 can attack this single article, which is of this
13 Acute Liver Failure Study Group, they can illustrate
14 that the rest of the medical community, the rest of
15 the scientific community, and the rest of the
16 regulatory community got it wrong.

17 In particular, they attack the Larson
18 study. And that -- I -- I assume you have a copy of
19 it, so I won't give you another copy of it, but that
20 article was designed to look at a bunch of things.

21 It was designed to look at the spectrum
22 of acetaminophen-induced liver failure seen in the
23 first six-years of this NIH-funded registry, from
24 1998 to 2003.

25 They didn't just study the 19 cases.

1 They studied 275 acetaminophen-induced acute liver
2 failure cases. And in that study, they reported
3 about half of the people in the study had attempted
4 to harm themselves by committing suicide.

5 But the important part of that study is,
6 about half of those patients were trying to get
7 better. They were trying to treat themselves, or
8 their doctors were trying to treat them, for pain.

9 Now, as part of that spectrum -- and --
10 and that's why it's important to talk about the big
11 picture here -- they described what they called the
12 low-dose cases, and those are the 19 cases that --
13 that Mr. Cohen talked to you about.

14 Now, Mr. Cohen spent a lot of time
15 talking about how medical histories are unreliable
16 and that somehow, the medical and scientific
17 community did not know that there were issues with
18 respect to the reported dosing history of some of
19 these cases.

20 Frankly, Your Honor, that's an
21 astonishing proposition because it's not true. In
22 the article itself -- and if you go to the article,
23 the page that Mr. Cohen did not cite for you -- on
24 page 1370, in the Discussion section of the paper,
25 they talk about the cases in which people are not

1 trying to commit suicide.

2 They say, among -- quote, among the
3 unintentional overdose patients, most reported that
4 they were taking the medication specifically for pain
5 and constitutional symptoms.

6 It goes on to say -- I'm skipping a
7 couple sentences -- why, then, the sudden onset of
8 severe liver injury? Our data suggests that there is
9 a narrow therapeutic margin and that consistent use
10 of as little as 7.5 grams a day may be hazardous;
11 however, precise information on dosing is often
12 difficult to acquire in some of the patients.

13 They told the readers of this article
14 that there are some patients -- and I say "some"
15 because, as I will show you, certainly not all --
16 some patients had difficulty giving and getting a --
17 a dosing history.

18 It's not -- it's not surprising that
19 Mr. Cohen would spend his time talking about those
20 some, but there are many other cases in this 19 in
21 which the dosing history was reliable, including the
22 dosing history provided by one of defendants' own
23 experts, unknown to him when he wrote his report.

24 Dr. Flamm and his medical center
25 provided a case, 010, in which the patient was

1 described by the -- by the -- by their institution as
2 having acetaminophen-induced liver failure, and
3 Dr. Flamm personally confirmed the low dose.

4 So while the defendant has spent a lot
5 of time talking about how unreliable this is and
6 picking apart little parts of the paper, not only did
7 the authors disclose that there was a problem with
8 some patients, they didn't talk about -- fairly talk
9 about the -- the breadth of the cases, of the 19
10 cases.

11 Now, I want to emphasize before I really
12 get into the argument in this case that this 2005
13 article is one of the lines of evidence that the FDA,
14 the ASLD, and the FDA Working Group relied on to
15 recommend that there be better instructions for
16 acetaminophen, that the dose be lowered, that the
17 margin of safety is too small, and that there is a
18 risk with this problem -- with this drug.

19 Now, to -- to -- having set up where
20 this argument fits in in the -- in -- in -- in the
21 spectrum of this case, now I want to turn to what
22 McNeil's attacks are and how this issue unfolded so
23 that we're here in early 2016 talking about this
24 instead of something that happened a long time ago.

25 To support its attack on this peer-

1 reviewed article, McNeil has procedurally collected
2 all the CRFs for the Larson study. They could have
3 focused on all of them, but they didn't. They chose
4 to focus on the 19.

5 THE COURT: Is it a problem with the
6 methodology that the authors of the report
7 acknowledge that they didn't look at the CRFs?

8 MR. TISI: No, because this is -- if you
9 look at the paper, Your Honor, the paper has
10 something in the range of, I think, 11 authors. Each
11 of them do a part of the paper.

12 Dr. Lee was involved in actually looking
13 at the CRFs, and he testified to that. Dr. --
14 Dr. Larson was -- her job was to take the information
15 that was in the spreadsheet that was provided as a
16 result of this process and collate it and -- and --
17 and write a first draft.

18 The important thing about the
19 methodology, Your Honor -- and Dr. Robuck testified
20 to this extensively, and it's in her declaration --
21 the procedures for collecting and analyzing the data
22 were not set up by the Acute Liver Failure Study
23 Group in a vacuum.

24 These were set up in connection with the
25 National Institutes of Health, which not only

1 approved and reapproved and reapproved the grant for
2 the -- for the Acute Liver Failure Study Group, but
3 the practices, including the Manuals for Operation,
4 including the data collection, including all of
5 that -- was approved by the F -- by -- by the
6 National Institutes of Health.

7 They had monthly steering committee
8 meetings, where -- Dr. Robuck sat in on those
9 steering committees, and these cases were -- were
10 presented and discussed, and any issues related to
11 the conduct of the Acute Liver Failure Study Group
12 were -- were conducted.

13 They had a once-a-year meeting of all
14 the investigators. And during the course of this,
15 any issues related to data collection were -- were --
16 discussed.

17 She testified that the low-dose cases
18 were specifically discussed, not only within --
19 within the -- within the ASLD themselves, but with
20 the NIH, and they were provided with summaries of
21 these patients.

22 She took those patients and went back to
23 what's called a data safety monitoring board, which
24 is an internal board -- it's described in her
25 declaration -- with the NIH. Dr. Lee and none of the

1 investigators were part of that.

2 The summaries of these patients were
3 provided so that any information, any problems with
4 data collection, with patient safety, with any
5 conduct of this study over the -- the almost 20 years
6 it's been -- it's been in effect, would be identified
7 by the -- by the data safety monitoring board and be
8 brought back to the Acute Liver Failure Study Group
9 and corrected.

10 And so while Mr. Cohen has spent a lot
11 of time taking apart individual cases, the truth of
12 the matter is, the methodology that was used by the
13 Acute Liver Failure Study Group was unique to almost
14 any study that I've been involved with in the years
15 that I've been doing this, in that it was
16 scrupulously supervised by the National Institutes of
17 Health, its procedures were subject to peer review,
18 its procedures and -- were subject to renewal every
19 three to five years, and it passed every single time.

20 In fact, Dr. Robuck -- I believe her
21 last question and answer in her deposition was, have
22 you ever seen a study that was more meticulously
23 done, even if there were flaws in various -- as will
24 inevitably happen in 20 years, that there would be
25 things missing in forms and those kinds of things,

1 but when you look at the conduct of the study, how
2 does it compare? And he (sic) said -- both Dr. Lee
3 and this study were remarkable in -- in their
4 contribution to the understanding of this -- of this
5 disease.

6 So to answer your question directly,
7 Your Honor, there were checks and balances for the
8 methodology that was employed for this study, the
9 data collection, the data analysis, and that was
10 provided by the National Institutes of Health.

11 So what happened in this case -- and
12 I -- I believe -- returning to my argument, what I
13 think we have to do is go back to where we were in
14 January.

15 The defendants produced a report. The
16 report's from three experts; a Dr. Brown, a
17 Dr. Flamm, and a Dr. Brent (ph). Importantly, and as
18 I'll discuss in a moment, none of these three
19 litigation experts have ever focused their research
20 activities on acetaminophen, on acute liver failure
21 related to any drug.

22 They're -- even though two of them were
23 members of the Acute Liver Failure Study Group,
24 remember, the Acute Liver Failure Study Group does a
25 lot of things other than study drugs. That was their

1 focus. They weren't studying acetaminophen.

2 But they come marching into this
3 courtroom in January with reports that say four
4 things, and we can't forget those four things because
5 it calls into question the methodology that they used
6 to analyze these cases.

7 They said, number one, many of these
8 cases didn't even have acute liver failure; they had
9 things like sepsis or shock or some other things;
10 many of them didn't even have acute liver failure.

11 Number two, they said, well, if they had
12 acute liver failure, they must have been due to other
13 things other than acetaminophen. They mentioned
14 things like hepatitis A. They mentioned things like
15 alcoholic liver disease or cirrhosis.

16 Number three, they say, well, in the few
17 cases that were actually acute liver failures --
18 acute liver failure and in those even fewer cases
19 that were due to acetaminophen, not one, not a single
20 one was a case that can qualify as low dose.

21 And they further argue, even though one
22 of them was listed as a participant in the study and
23 the other one, in fact, participated in the study,
24 said the article ought to be retracted and should not
25 be -- should not have been published in the first

1 place.

2 Now, over the past two months, we have
3 provided declarations to the court of the following
4 people so the court understands and the record is
5 clear as to who they are.

6 William Lee is the private
7 investigator -- the principal investigator for 20
8 years for the Acute Liver Failure Study Group and the
9 holder of the NIH grant and the senior author of the
10 Larson study. He's authored close to 150 articles on
11 acute liver failure and acetaminophen toxicity. He
12 was not retained or paid a dime.

13 Anne Larson was the site investigator
14 and lead author for the Larson article. She's
15 published over 30 articles on acetaminophen-induced
16 liver failure. She has not been paid a dime.

17 Dr. Robuck, the NIH fund official in
18 charge of the NH- -- Acute Liver Failure Study Group
19 grant, she was not retained and has not been paid a
20 dime.

21 I emphasize this to note that these
22 willing -- that these patients -- that these doctors
23 were willing to come forward at -- at -- at
24 tremendous time and on short notice to provide the
25 declarations that are before the court.

1 In addition, we provided the reports of
2 Dr. Kaplowitz, who was the acute -- who is widely
3 considered one of the nation's authorities on -- in
4 this area and published a textbook on -- on
5 drug-induced liver disease; Dr. Davern, who was a
6 site investigator and author on the -- on the Larson
7 paper, and two toxicologists.

8 I go through this because I think you
9 need to understand -- sometimes I watch on television
10 people debating issues, and sometimes it is important
11 to understand where they stand in the medical and
12 scientific community because not all opinions are
13 equal.

14 I have provided in your book as tab 1 a
15 chart that we put together, and I'd just like to take
16 a moment and go through them, because I think --
17 against the backdrop of the argument you just heard,
18 I think you need to see where these experts line up.

19 Publications on -- on acetaminophen,
20 acute liver failure, and drug-induced liver injury,
21 Dr. Lee, 152 articles; Dr. Kaplowitz, 88; Dr. Davern,
22 34, Dr. Larson, 36.

23 Dr. Brown has had six, and Dr. Flamm has
24 had one. And they go through each of these
25 article -- each of these on -- reports of acute liver

1 failure, acetaminophen. These are not --
2 respectfully, while they may be -- while they may be
3 experts in the fields in which they are -- hepatitis
4 and other areas, liver transplants, they are not
5 experts in the field of drug-induced liver disease or
6 of acetaminophen-induced liver failure.

7 In fact, just to illustrate the point,
8 Dr. Flamm himself was asked to write -- author a book
9 on liver disease. Interestingly -- and it's tabbed
10 in your book -- the person he asked to write the
11 chapter on drug-induced liver disease was Dr. Davern.

12 So now, what do these qualified experts
13 and witnesses say? You've heard nothing from
14 Mr. Cohen about the analysis performed by any of
15 these witnesses.

16 McNeil's experts failed to consider
17 important evidence when they drafted their report,
18 including the presence of acetaminophen adducts that
19 was subsequently performed on these low-dose cases.
20 I think Your Honor cued into that in one of the
21 questions you asked Mr. Cohen.

22 If you turn to the Lee declaration,
23 page 14 and 15, he describes the importance of
24 acetaminophen adducts. And I have a copy if Your
25 Honor needs it. But on pages 14 or -- and 15 --

1 THE COURT: Hang on.

2 MR. TISI: -- he talks about having
3 received the expert reports of Drs. Brown and
4 Dr. Flamm and Dr. Brent (ph), and as a scientist, he
5 was concerned; did I get it wrong?

6 And one of the things he did was go back
7 and look and see -- you know, we have this new test
8 that we had done for acetaminophen toxicity; we know
9 these patients had toxicity -- we know these patients
10 had acute liver failure; did we, in connection with
11 another study we had done -- and there were several
12 studies -- actually test these patients for
13 acetaminophen adducts? In fact, they had.

14 That would be the first question that
15 a -- that an expert who was looking at things in an
16 unbiased fashion would ask. It's the question that I
17 would have expected Dr. Flamm and Dr. Brown, who were
18 members at one point of the Acute Liver Failure Study
19 Group, to have asked; by the way, McNeil, are there
20 adducts levels on these patients, and can you get
21 them for me, because I'm about to write a report that
22 says some of these patients don't even have
23 acetaminophen toxicity.

24 Now, it's important to understand what
25 these adduct levels -- because I suspect you're going

1 to hear from Mr. Cohen about what these adduct levels
2 show and what they don't show.

3 If you go back to the chart that I
4 provided to you about the publications of the various
5 experts in this case, you will learn that plaintiffs'
6 experts and Dr. Lee and Dr. Larson have published on
7 acetaminophen adducts. They are the primary
8 publishers of this issue -- on this issue and what
9 they mean.

10 Defendants' experts have not published a
11 single article or have ever given a talk, to my
12 knowledge, about acetaminophen -- acetaminophen
13 adducts.

14 Dr. Lee testified in his deposition --
15 and it was very clear -- that the presence of adducts
16 only shows you that there is acetaminophen toxicity.
17 It tells you nothing about how much -- how -- the
18 dose that the patient took. I suspect you're going
19 to hear Mr. Cohen get up and say, oh, by the way,
20 these high adducts correlate with high dose. They
21 don't.

22 The other thing, interestingly, that --
23 that these experts say -- point out is, well, why
24 didn't the defendant ask about genetic polymorphisms?
25 As you see from Dr. -- Dr. Lee's declaration, many of

1 these same patients were subject to genetic testing
2 to see whether there were common -- common genetic
3 features which would explain why patients developed
4 acute liver failure at low doses.

5 And, lo and behold, in a patient called
6 Kort (ph), patients -- they studied 6 grams or less,
7 but -- but the 4-gram patients were in that group --
8 showed a common genetic polymorphism which would
9 explain -- which would help to explain why some
10 people get risk and the other people don't.

11 The fact that McNeil's experts never
12 sought that data or -- and, as experts, didn't even
13 care to ask for it says a lot about the analysis
14 that's before you.

15 They failed to consider the fact -- and
16 this is something that Dr. Flamm didn't realize until
17 Dr. Lee pointed it out to him, that one of the
18 low-dose cases was actually confirmed by his site and
19 that Dr. Flamm confirmed the dose.

20 They failed in their reports to discuss
21 that which they had made a big deal previously, that
22 it didn't exist, that there was no patient in any
23 United States hospital that ever got acetaminophen
24 under the supervision of a doctor who got acute liver
25 failure at 4 grams or less. There was such a case in

1 these 19.

2 So against the backdrop, not only must
3 you consider what the acute liver failure authors
4 say, you have to consider the source of an -- not
5 only -- the quality of the expert reports that are
6 put before you to challenge that.

7 So the court will have to decide in this
8 Daubert hearing not only whether the Daubert
9 challenge has a basis and (sic) whether, ultimately,
10 any of the data that you hear in this case goes to --
11 to the jury.

12 So with that as a background, I'm now
13 going to shift a little bit to talk about the big
14 picture, the big picture of where -- defendants'
15 analysis of the Acute Liver Failure Study Group
16 article and the article itself, what it says, and
17 whether it even makes a difference.

18 First of all, I'd like to point out that
19 under Daubert, peer review is not necessary, but when
20 it exists, it's a very important indicia of
21 reliability. The reliability is even higher, and the
22 courts presume it's even higher, when the study is
23 done independent of and prior to litigation. And
24 it's at its highest when regulatory authorities like
25 the FDA or the NIH rely on the study.

1 And even though I couldn't find a case
2 that says what I'm about to say, I would submit that
3 the reliability is even higher when the study is not
4 only relied on by the FDA and the federal government
5 but is funded by it and is peer-reviewed by it.

6 And I will emphasize that Dr. Robuck
7 indicated that this study was submitted to the FDA
8 prior -- was submitted to the National Institutes of
9 Health prior to it being published, and nobody said,
10 you know, I'd like to see the methodology for these
11 low-dose cases. Nobody said, you know, this doesn't
12 make any sense; we'd like to see the -- the case
13 report forms. Nobody said that this -- this doesn't
14 jive with the medical and scientific literature that
15 is already out there in the medical community.

16 I'd like to point out that no -- no
17 questions were ever raised until this past six months
18 on this study, not the NIH, not the FDA, not the
19 Journal of Hepatology; importantly, not Dr. Brown,
20 not Dr. Flamm, who were part of the Acute Liver
21 Failure Study Group and could have done so at any
22 time.

23 Nobody suggested that they do this
24 so-called body burden calculation that they -- that's
25 woven throughout all their reports and we'll talk

1 about in a moment.

2 Yet they claim that this process was
3 flawed, and their experts never sought to explore the
4 process.

5 Now, I really want to talk about
6 Dr. Brown, why this is so -- why what's going on in
7 this courtroom has not played out in the medical and
8 scientific community, and I'm going to give you two
9 examples.

10 In tab 3 of your binder is a series of
11 emails that were produced in Dr. Davern's deposition,
12 and they're ones that the court has not yet seen but
13 I think is telling and illustrates as to what a farce
14 this proceeding has become.

15 In your binder, Dr. Brown was asked --
16 as you recall from the papers that we filed,
17 Dr. Brown was asked to resign from the Acute Liver
18 Failure Study Group in the mid-2000s because of his
19 inattention to the group, his failure to enroll
20 cases, his failure to employ the proper paperwork.

21 Nevertheless, because he had been -- and
22 this is before any of this issue came up. Before he
23 had been an -- because he had been an investigator in
24 the past, Dr. Lee, on behalf of the Acute Liver
25 Failure Study Group, asked Dr. Brown to participate

1 in a new study, a five-year retrospective analysis of
2 Acute Liver Failure Study Group cases.

3 That happened in 2015, while acting as
4 McNeil's expert. And you'll see that there are two
5 emails there. There's one in 2016 and 2015.

6 Importantly, this publication included a
7 subanalysis of over a hundred acetaminophen-induced
8 acute liver failure study groups in the Acute Liver
9 Failure Group registry.

10 You will see in there a March 29, 2016
11 email from Dr. Brown, two months to the day after he
12 filed his expert report in this courtroom, saying
13 that the Acute Liver Failure Study Group doesn't know
14 how to analyze an acute -- doesn't know how to look
15 at a case of acute liver failure, doesn't know how
16 to -- you know is sloppy in its analysis of acute
17 liver failure related to acetaminophen, and he puts
18 his name on a paper that is going to be published --
19 or has been published relating to the analysis of
20 Acute Liver Failure Study Group and acetaminophen.
21 It doesn't talk about dose issues, but it talks about
22 the first two issues we talked about before.

23 Because if you recall, Your Honor,
24 before, the initial report of Dr. Brown is, these
25 patients don't even have acute liver failure, and if

1 they have acute liver failure, it's probably not due
2 to acetaminophen.

3 Yet Dr. Brown, outside the courtroom, is
4 putting his name to an article by the Acute Liver
5 Failure Study Group as now marching into this court
6 saying that these guys don't know how to do anything,
7 and they're unreliable.

8 Now, if you take away anything from the
9 Daubert -- from the Daubert standard, it's that
10 experts are supposed to employ the very same
11 methodology in the courtroom that they apply in their
12 daily life as a scientist and as a doctor. I
13 question whether or not Dr. Brown meets that
14 standard.

15 I'll bring another point --

16 THE COURT: Mr. Tisi, in this tab,
17 there's a March 29, 2016 email. It looks to be from
18 Dr. Brown. He says, I added my comments. Are those
19 comments then on the attached text?

20 MR. TISI: Yes, they are -- they are --
21 they are on the attached.

22 THE COURT: Okay.

23 MR. TISI: In other words, he's --
24 he's -- he's giving approval to the study and not
25 saying -- you know, in that email, there's nothing

1 that says, you know, wait a second; I've just been
2 involved in a proceeding and I wrote a report two
3 months earlier where we have a real problem with --
4 with -- with the Acute Liver Failure Study Group's
5 methodology; I'd like to see the case report forms.

6 You would think -- I mean, if I was --
7 if I had a law clerk who wrote a bad memo for me
8 on -- on January 30th and I get a new memo on the
9 same topic on March -- on March 30th, I'd say, I'd
10 really like to see the data upon which you -- which
11 you rely. Dr. Brown didn't do that.

12 I'm going to give you another example as
13 to why this is a -- a difficult argument for the
14 defendants to make. Exhibit Number 21 to our motion
15 is case 12. It's patient 010, which is Dr. Flamm's
16 patient.

17 In his January 29th report, Dr. Flamm
18 analyzed the 19 cases. It included an analysis of
19 patient 12. In his report, he said the cause should
20 not be listed as acetaminophen and that the dose is
21 unreliable. And, further, he said it would be
22 unreliable for anyone -- anyone on -- any reasonable
23 scientist to describe this as a low-dose case.

24 But unbeknownst to Dr. Flamm when he
25 wrote his report and as described in Dr. Lee's

1 declaration at page 10, 11 and page 34 and 37, this
2 was a report -- this was a report of a case out of
3 Dr. Flamm's -- out of Dr. Flamm's site. His site
4 contributed the case.

5 His site, and maybe even him, said it
6 was acetaminophen-induced liver failure. His site
7 described a biopsy as consistent with drug-induced
8 liver disease. And as we learned, as you see as
9 attached to Exhibit 7 to his -- to Dr. Lee's
10 declaration, Dr. Flamm himself confirmed the dose as
11 less than 4 grams.

12 Now, you saw Mr. -- Mr. Cohen -- I -- I
13 thought it was interesting that Mr. Cohen brought up
14 the important parts of this form, and I -- and I wish
15 I could ask him to bring up that part. And he said
16 there was several -- I don't know if you'll recall
17 that he said there was several important parts of the
18 form I want you to focus on.

19 I thought it was interesting that one
20 part of the form he didn't focus on -- and all of
21 these reports --

22 And if I can -- I only have one copy,
23 and if I can, I will give you my copy of Dr. Flamm's
24 report. May I approach, Your Honor?

25 THE COURT: Yes.

1 MR. TISI: This is Exhibit 12 out of the
2 binder. And if I could argue from this for a moment
3 because I only have one copy?

4 THE COURT: Sure.

5 MR. TISI: You will notice that there is
6 a -- it has two forms. Each of these consist of two
7 forms. There's an admission to the study form and an
8 outcome form. One is filled when the patient is
9 enrolled, and the other one is admitted when -- after
10 the patient is analyzed.

11 And there is a section -- give me --
12 bear with me a moment.

13 I'll have to find it, Your Honor. It's
14 the final diagnosis of a patient. I have another
15 form here (indiscernible).

16 THE COURT: Thanks.

17 MR. TISI: It's where the medical doctor
18 indicates what the -- what the final diagnosis of the
19 patient is, and it indicates on this case that the
20 patient -- it's a little box, and they fill it in.
21 It says, acetaminophen. It doesn't say
22 indeterminate. It doesn't say idiopathic. Their
23 site, Dr. Flamm's site, said this was
24 acetaminophen-related.

25 And, of course, we also know that

1 they -- that the -- that in realtime, in real
2 science, Dr. Flamm and his colleagues were correct.

3 How do we know that? Well, we know that
4 because if you go to table 1 of Dr. Lee's
5 declaration, this patient was adduct-positive. The
6 patient had the presence of acetaminophen adducts.

7 So Dr. Flamm -- and the reason for me
8 bringing you -- bringing this up to you is that
9 Dr. Flamm, in his litigation report, says, there's no
10 way that this could possibly be acute liver failure
11 due to acetaminophen; nobody would ever say that; the
12 dose is unreliable, and we come to learn that his
13 site made the conclusion that it was acetaminophen,
14 we know the adducts were positive, and Dr. Flamm
15 confirmed the dose.

16 So let's talk about the issues in the
17 case. First of all, defendants filed on Friday issue
18 one; should you strike the declaration of Dr. Lee?
19 That issue wasn't raised by Mr. Cohen. If -- do you
20 want me to find that portion of the -- of the -- of
21 that form? Would that help?

22 Okay. Number one, should you strike the
23 declaration of Dr. Lee? McNeil filed a motion last
24 Friday to strike the Lee declaration. We filed our
25 opposition yesterday. I just want to discuss it very

1 briefly --

2 THE COURT: Okay.

3 MR. TISI: -- because I think it is
4 important.

5 Respectfully, it is a bizarre request.

6 The law encourages lawyers such as myself to

7 thoroughly investigate and do exactly what I did.

8 When we had the motion that was filed, we contacted

9 the lawyers for Dr. Lee. We sent Dr. Lee, through

10 his counsel, the reports of Drs. Brown, Flamm, and

11 Brent (ph) and the -- and the -- and the motion that

12 was filed on behalf of Dr. -- on behalf of McNeil.

13 They were read by Dr. Lee before I ever

14 had a chance to meet with him. I met with him in

15 mid-February. He did most of the talking. He -- he

16 gave us the information. We took the information

17 down. We turned around a declaration. We sent it to

18 his lawyers. Drafts went back and forth, and he

19 signed the -- he signed it.

20 I will point out that McNeil did exactly

21 the same thing with the declaration that it provided

22 in January. It drafted the report. It drafted the

23 declarations, sent it to the lawyers, had it signed,

24 and it was submitted to the court.

25 So I would argue that the motion they

1 filed on Friday is not only frivolous but is designed
2 to get the court not to look at the substance of it.

3 There are, however, two corrections that
4 Dr. Lee made in his deposition, so I -- I want to
5 call it to the court's attention.

6 In paragraph 14, he used the word
7 "median" instead of "mean" when describing the median
8 dose being 7.5 grams in the Larson study.

9 The second is paragraph 41, which was
10 left in by accident. He testified to that.

11 As to the remainder of the 48-page,
12 single-spaced declaration, it remains his opinion as
13 of today.

14 Issue number two; does the fact that
15 there is 17 reported cases, and if there are 16 or 17
16 or 18 cases that remain after the reanalysis, based
17 upon what we now know, does it make a difference?

18 It really doesn't. The point in
19 describing the low-dose cases was not to give a
20 conclusion as to causation but to describe the
21 low-dose phenomenon in the Acute Liver Failure Study
22 Group data. It's a descriptive paper. It fits into
23 all of the other articles that are out there in the
24 peer-reviewed public's literature.

25 There is a statement in the article that

1 indicates -- that they can use at trial that says
2 some of the patients can have a difficulty giving
3 medical history -- giving dosing history. But some
4 don't.

5 But there are also reasons why some of
6 the patients in this -- in the dosing -- in this
7 group are reliable. One would be case number 9,
8 that's described in Dr. Lee's declaration, ending in
9 also 010.

10 And -- and I just want to be clear,
11 there are -- even though we can't use the prefix for
12 these studies under the agreement with the Acute
13 Liver Failure Study Group -- they're giving patient
14 identifying information -- and -- and just
15 coincidentally, the case that Dr. Flamm has, which is
16 case number 12, ends in 010. Case number 9 from
17 another institution ends in 010. They're two
18 different cases, just so that -- it may be confusing,
19 but -- but you can see that there.

20 THE COURT: I see it.

21 MR. TISI: That case is a case -- as I
22 indicated, is a hospitalization case where the
23 patient got 12.5 grams over five days. If the
24 patient was -- was being given acetaminophen in a
25 hospital setting, they would have gotten no more than

1 4 grams a day, which fits exactly the pattern of
2 being in the hospital for five days.

3 So what remains after this study is, if
4 you substituted the -- the -- the number 17 or 16 for
5 19 -- is, you still have a description of acute liver
6 failure with patients who took 4 grams or less.

7 It is not what the defendants came
8 marching into court with in January, which is, not a
9 single one of these patients are reliable; not a
10 single one -- most of these patients don't even have
11 acute liver failure or acetaminophen-induced liver
12 disease. That argument is, apparently, out the
13 window because of the adducts testing.

14 So now they're focused on a handful of
15 cases, and the question is, does it make a
16 difference? I question -- and I raise this because
17 if the study had written, for the purposes of the
18 jury and purposes of reliability -- if the jury had
19 heard that there was 17 cases or 16 cases of acute
20 liver failure at less than or equal to 4 grams,
21 the -- the -- the observation would be exactly the
22 same.

23 Now, I want to go to number three, a
24 third issue; what do the acetaminophen adducts show?
25 Now, in the reports, McNeil's experts, as -- as we

1 had indicated, indicate not only was the dose
2 unreliable, but these patients don't even have acute
3 liver failure. I think -- as I indicated, I think
4 that's kind of out the window now.

5 Table 1 of the Lee declaration on
6 page 15 indicates that for the acetaminophen patients
7 who were tested, 18 of them, 18 of the 19, 16 were
8 adduct-positive. One of those patients was tested
9 too long after the patient had been exposed, so the
10 adduct test would be unreliable. So that there was
11 only one patient, which happens to be the Macrobid
12 case that Mr. Cohen talked to you about, that was --
13 should not be included.

14 While these -- while this test is not
15 commercially available, they are the smoking gun to
16 show acetaminophen was a cause of acute liver failure
17 in these patients, but this shows nothing about dose.

18 It shows that the Acute Liver Failure
19 Study Group investigators were largely right in their
20 non-litigation study, and McNeil experts were mostly
21 wrong in their litigation reports.

22 That is a really important point here,
23 Your Honor. They came marching in here in January
24 saying -- saying that, based upon their -- their post
25 hoc analysis of these cases, that these cases weren't

1 even acute liver failure or related to acetaminophen.

2 The acute liver failure -- and it
3 indicates why there is an indicia of reliability
4 accorded to studies like this and a skepticism of
5 post-study analysis like that done by the Acute --
6 by -- by McNeil's experts.

7 THE COURT: Let's wrap it up, Mr. Tisi.

8 MR. TISI: Okay. In your binder, there
9 is a -- there is a quote from Dr. Lee on page 21, and
10 I asked him, if anyone were to stand up in court and
11 say the presence of acetaminophen adducts tells you
12 anything about dose, would that be true? The answer
13 is no.

14 Let's talk about this half life issue
15 because it involves our -- our request that these
16 experts be struck.

17 In their reports, McNeil's reports rely
18 on a formula, and the formula is basically this:
19 Measure the acetaminophen in the person's body at the
20 time that the person presents; look at their blood;
21 assume a half life of that patient; calculate
22 backwards; and through this, you can calculate and
23 demonstrate that the dosing history given by the
24 patient is incorrect .

25 The problem with that -- that -- that

1 hypothetical calculation is -- is several. Number
2 one, it doesn't -- it doesn't describe the phenomenon
3 that as a patient is in acute liver failure, they
4 continue to -- and if they're taking acetaminophen,
5 it continues to accumulate in the liver. It's not
6 excreted. So it gives a high level -- an
7 inappropriately high level.

8 It is also important to note that not
9 only does the plaintiffs' experts -- not only does
10 Dr. Lee and Dr. Larson -- but defendants' own experts
11 agree that that test has never been validated in a --
12 in a situation involving acetaminophen.

13 So, for example, Dr. Flamm, as indicated
14 in his deposition on page 107 and 108 --

15 Well, we asked this of Dr. Brent (ph).
16 From your bibliography, are there any articles that
17 this estimated body burden -- the way you did it in
18 your supplemental report? And the answer, from
19 acetaminophen? Yes. No.

20 We asked Dr. Flamm, there is -- question
21 on page 286: There is no study that says --
22 question: Is there a study that says that if we
23 combine body burden with an estimated half life, we
24 can determine whether a dose reported in a patient in
25 a chronic dosing situation is accurate; that has

1 never been proven or attempted to be proven, true?

2 Answer: There is no such study.

3 Dr. Lee agrees. Dr. Kaplowitz agrees.
4 Dr. Davern agrees. Everybody agrees that this is not
5 a formula that has ever been validated in the realm
6 of science in any study that will demonstrate the --
7 that -- that dose.

8 And I would point out that Dr. Brown,
9 Dr. Flamm has never recommended that the -- that the
10 Acute Liver Failure Study Group employ such a -- such
11 a thing.

12 And I would also point out, in reality,
13 that the FDA has been struggling with the issue of
14 confirming dose for 15 years. You would think that
15 in that time, McNeil would have come forward and
16 said, you know something; FDA, we found the Holy
17 Grail; we have a -- we have a -- a formula that all
18 you have to do is plug in a couple numbers, and we
19 can demonstrate that all this concern about low-dose
20 ingestion and margin of safety is a bunch of -- is a
21 bunch of hooley.

22 They never did that, but they march into
23 court and put a declaration before Your Honor, put
24 a -- put a -- put a -- a report before Your Honor
25 that says -- that says that they've never published

1 on it, and we're supposed to -- we're supposed to
2 allow them to present that under the guise of
3 science.

4 So we would ask not only that that be
5 struck as unreliable and -- and -- and contravening
6 Mr. -- Dr. Lee and -- and everybody else, but their
7 experts be struck -- struck on that.

8 The truth is this, Your Honor, and --
9 and -- and -- and it is difficult, and this I agree
10 with Mr. Cohen on. It's difficult to discuss each
11 and every one of these cases.

12 But I did ask Dr. -- I did go through
13 these -- these cases on Friday with Dr. Larson, and I
14 said, Dr. Larson, we can't go through each one of
15 these individually, but let's -- let me ask you this
16 as a -- as a --

17 And I can provide you with this
18 testimony. And I did this with Dr. Lee as well.

19 -- let me ask you in the spectrum, are
20 there cases in the 19 in which the dosing history was
21 more challenging? Yes. Are there cases within the
22 19 where the dosing history was less challenging?
23 Yes. Is that to be expected? Yes, it's to be
24 expected because patients -- because doctors
25 sometimes find that patients can give accurate

1 histories, and sometimes they don't, but we accepted
2 the patients' history, and we described what we saw.
3 Does that mean that there's not contradictory
4 information for some of them? Of course, there is.
5 But does that mean that the results of the study
6 is -- are wrong as reported? Of course not.

7 The defendant has a lot of arguments
8 that it can make at trial that dosing history is
9 sometimes difficult. I expect that that's going to
10 be a major thrust of their -- of their argument.

11 That has never been in dispute. Dr. --
12 Dr. Lee and Dr. Larson include that -- admit that
13 freely. It's in their declaration. It's -- it's
14 throughout the medical literature.

15 Does that mean dosing history is
16 unreliable? Sometimes it may be; sometimes it may
17 not be. They were reporting what they saw. And
18 that's what this paper is about, and that's why it's
19 an important paper. It fits in the -- in the
20 spectrum of cases out there.

21 I'm going to wrap up now. We've talked
22 about -- I just wanted to wrap in here that we have a
23 challenge to the defendants' experts. I think they
24 went out way on a limb, way beyond where an expert
25 ought to be. They became advocates in this case, and

1 I believe that they -- that they should be struck for
2 the reasons in our motion.

3 I would point out, Your Honor, that
4 sometimes enough is enough. We've been through this
5 for about a year and a half. We've argued every
6 single issue that you could possibly have. This is
7 the time to put an end to this constant wrangling
8 about what the data mean and allow the parties to put
9 their evidence, put their proofs before a jury, and
10 the Larson paper's one of them.

11 Thank you very much.

12 THE COURT: Thank you, Mr. Tisi.

13 All right. We're going to break.

14 Do you have something else you want to
15 argue Mr. Cohen?

16 MR. COHEN: I wanted to respond. Two
17 minutes.

18 THE COURT: All right. You have two
19 minutes.

20 MR. COHEN: Thank you, Your Honor, very
21 much.

22 You know, there's an old -- a movie
23 about handling the truth. Well, I'm going to say
24 that about the dose. This is all about dose, and the
25 plaintiffs can't handle the dose.

1 The adduct data, as Mr. Tisi correctly
2 said, does not establish that these are low-dose
3 cases. Their own experts all admitted that. Dr. Lee
4 admitted that. Dr. Larson admitted that. All of
5 their experts have admitted that. The low -- the
6 high adduct data does not establish that any of these
7 cases occurred at low dose.

8 And it gets worse, Your Honor. Do you
9 remember the movie "A Christmas Story," where the
10 mother says, Ralphie, you're not going to get that BB
11 gun for Christmas because you're going to shoot your
12 eye out?

13 I think this gun has misfired. If we
14 could put up (indiscernible), the 2011 study
15 published by the ALFSG with Dr. Larson as a coauthor,
16 Dr. Lee as the primary author, here's what it says:
17 1.0 nanomoles of adducts indicate a definite
18 acetaminophen overdose.

19 They didn't put that in the declarations
20 they submitted, and then they learned this at our
21 expert's depositions that, oh -- oh, my God; the gun
22 misfired. The smoking gun we just heard about, it
23 misfired. All their adduct levels are between 3 and
24 41 nanomoles per milliliter.

25 I invite you to look at the very table

1 Mr. Tisi just put before you. They wrote that, and
2 they published that. And that's the Acute Liver
3 Failure Study Group, and that is why the adduct data
4 now, we're being told, doesn't establish dose. Oh.
5 Oops. It establishes overdose. They don't want you
6 to know that.

7 THE COURT: And do I have that article?

8 MR. COHEN: May I approach?

9 THE COURT: Thank you. Thank you.

10 MR. COHEN: One last thing. They --
11 they talked a lot about Dr. Brown. They brought your
12 attention to Dr. Brown's emails. They were offered
13 Dr. Brown's deposition. They declined. Dr. Brown's
14 not here to explain his emails. I would ask the
15 court not to consider that evidence as -- as anything
16 other than hearsay and unrelated.

17 Finally, Mr. Tisi talked about
18 polymorphism. Dr. Lee testified that his papers on
19 genetic testing contain no data about 4 grams or less
20 ingestion of acetaminophen at page 322 of his
21 deposition, lines 3 through 7; we didn't discuss the
22 quantities in the papers -- two papers.

23 Finally, Your Honor, it is a problem,
24 the methodology used for a study that the plaintiffs'
25 experts are relying on, and it's a bigger problem

1 when the authors of that paper actually excluded the
2 cases in 2009 and didn't tell the scientific
3 community and didn't tell this court.

4 Thank you.

5 THE COURT: Thank you, Mr. Cohen.

6 Mr. Tisi, you may have your case report
7 back.

8 MR. TISI: Okay.

9 THE COURT: Thank you very much --

10 MR. TISI: Can I make one --

11 THE COURT: -- for your written
12 submissions.

13 MR. TISI: Can I make one point about
14 this case report, Your Honor, because I think it
15 is -- it is -- Mr. -- Mr. -- with your indulgence,
16 about 30 seconds?

17 THE COURT: Okay.

18 MR. TISI: I asked -- and it's in your
19 binder -- about this adduct issue of the -- this --
20 this backfiring smoking gun issue. Every single
21 witness said, it measures toxicity; it doesn't
22 measure dose.

23 But to illustrate that point, I would go
24 to the case 010, which is number 12.

25 THE COURT: Um-hmm.

1 MR. TISI: And that case, as we know, is
2 a 4-gram case because it was in a hospital. That
3 patient had a -- a 9. And if that patient had a 9
4 adduct level, it does -- it would demonstrate that
5 patient had a normal dose and had a 9. That
6 demonstrates that -- that this measures toxicity but
7 doesn't measure dose, as Mr. Cohen just told you.

8 Thank you very much, Your Honor.

9 THE COURT: Thank you.

10 MR. COHEN: Your Honor, one housekeeping
11 matter?

12 THE COURT: Yes.

13 MR. TISI: We do have the graphics
14 printed out.

15 THE COURT: Okay.

16 MR. COHEN: Do you just want a set?

17 INDISCERNIBLE SPEAKER: Could I have a
18 set?

19 MR. COHEN: Yes.

20 INDISCERNIBLE SPEAKER: Thank you.

21 THE COURT: Could I see Ms. Jones and
22 Mr. Tisi for just a moment back in chambers?

23 ESR OPERATOR: All rise.

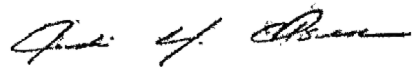
24 (Whereupon, the proceeding was concluded
25 at 12:23 p.m.)

C E R T I F I C A T I O N

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

I, Judi Y. Olsen, Registered Professional Reporter, do hereby certify that the foregoing is a true and correct transcript from the electronic sound recordings of the proceedings in the above-captioned matter.

April 29, 2016
Date



Judi Y. Olsen, RPR

A				
AASLD 21:15	85:11,13 88:24	adduct 33:17,19	13:13 14:14 15:10	42:15,25 43:2,7
23:16	89:24 90:6,16	74:25 75:1 90:10	15:14,16,19,22	44:3 45:5 49:1,10
aberration 45:8	91:1,11,19 92:4	97:1,6,23 98:3	16:6,8,12,15,19	51:2,4 54:2 61:13
ability 7:4	92:12,19 97:18	99:19 100:4	16:21 17:3,8,15	68:21 69:6 91:12
able 4:15 8:1 22:13	98:20	adducts 34:4,7	18:17,24 19:9	92:18 93:2
23:12,21	acetaminophen's	73:18,24 74:13,20	23:3 24:2,8 25:13	answered 18:4
above-captioned	61:7	75:7,13,15,20	25:13,23 26:12	answers 48:7
101:8	acetaminophen-i...	85:6,14 89:13,24	42:10,12 43:6,20	antibacterial 33:12
abstract 13:8 36:15	54:7 62:22 63:1	91:11 97:17	44:22 45:15 46:21	anybody 49:3
accept 50:2 51:7	65:2 71:15 73:6	adduct-positive	47:24 48:5,25,25	apart 65:6 68:11
acceptable 44:13	80:7 83:6 89:11	85:5 90:8	49:2,4 50:24 51:6	apparently 89:12
accepted 41:17	acetaminophen-r...	administered 57:9	56:9,24 97:15	appear 48:7
95:1	84:24	57:11	allow 53:15 94:2	APPEARANCES
accident 87:10	acknowledge 66:7	admission 51:18	96:8	1:9 2:1
accommodate 8:1	acknowledges 18:6	84:7	allowed 42:15,16	appears 61:24
accorded 91:4	22:2 56:20	admit 42:14 95:12	ALT 40:3	applies 52:4
accumulate 92:5	acquire 64:12	admits 31:14 38:2	altered 26:13 35:22	apply 81:11
accurate 92:25	acting 80:3	42:2	alternative 33:24	approach 11:18
94:25	activities 69:20	admitted 3:13	Alyson 2:5 9:17	32:3 83:24 98:8
accurately 8:18	actual 12:11	48:16 51:19 84:9	Alyssa 53:9	appropriate 44:4
acetaminophen 1:4	acute 6:15,19 7:7	97:3,4,4,5	amass 52:19	approval 81:24
12:7 13:4,14 14:1	12:4,7 14:6,11,15	advisory 15:3	ambiguities 24:25	approved 44:22
14:5,12,24 15:2,8	18:8 33:13 51:8	20:23 21:5 23:12	American 21:14	67:1,5
15:20 17:5,20	54:7 56:4 57:12	45:15 62:7	62:5,6	April 1:5 101:13
18:2,8 19:1,4,4,17	59:20 60:4,7,9,22	advocates 95:25	amount 8:20 50:8	area 72:4
20:6,10,24 21:6	61:4 62:5,7,13	age 41:12	amounts 50:2	areas 73:4
21:22 22:1 26:6	63:1 66:22 67:2	agencies 45:1	analyses 30:10	argue 10:12,15
27:1,2,6,10,11,18	67:11 68:8,13	agenda 4:3	analysis 69:9 73:14	11:11 70:21 84:2
29:23 30:17,18	69:20,23,24 70:8	agent 33:12	76:13 77:15 80:1	86:25 96:15
32:11 34:21,25	70:10,12,17,18	ago 19:20 22:12	80:16,19 82:18	argued 96:5
36:4,6,13,17 37:6	71:8,11,18 72:2	24:4 27:18 38:22	90:25 91:5	argument 3:3 7:8
37:18 38:1,15	72:20,25 74:10,18	65:24	analytical 17:9	7:22 10:23 53:5
39:2,8,13,24 40:2	76:4,24 77:3,15	agree 17:18 92:11	51:5	57:24 65:12,20
40:4,6,10 41:23	78:20 79:17,24	94:9	analyze 51:10 70:6	69:12 72:17 82:13
50:13,23 51:9,11	80:2,8,8,13,14,15	agreed 17:1 35:12	80:14	89:12 95:10
54:9 55:20,24	80:16,20,25 81:1	agreeing 52:15	analyzed 82:18	arguments 6:23
56:10 57:9 59:17	81:4 82:4 85:10	agreement 88:12	84:10	95:7
59:23 61:3,17	87:21 88:12 89:5	agrees 93:3,3,4,4	analyzing 66:21	article 14:10 19:9
65:16 69:20 70:1	89:11,19 90:2,16	Ah 40:16	Angeles 37:6	19:24 20:5,9,15
70:13,19 71:11	90:18 91:1,2,5	alcohol 26:16 34:14	animal 57:18	20:18 23:6,9
72:19 73:1,18,24	92:3 93:10 98:2	35:25 36:25	Anne 71:13	31:11 58:8 62:12
74:8,13,23 75:7	add 9:22	alcoholic 70:15	annotated 20:4	62:20 63:22,22
75:12,12,16 76:23	added 81:18	ALF 14:13 15:7,21	annual 21:16 23:16	64:13 65:13 66:1
80:17,20 81:2	addition 72:1	17:7,16,22 18:12	answer 12:10 17:5	70:24 71:14 72:25
82:20 84:21 85:6	additional 8:17	19:1 39:2,12,25	17:15,20 22:21	75:11 77:16,16
	24:24 27:7 52:5	43:20 50:24	28:6 30:24 35:8	81:4 87:25 98:7
	address 4:9 15:19	ALFSG 12:18	38:25 39:2 41:12	articles 20:17 58:9

71:10,15 72:21 87:23 92:16 ASHCRAFT 1:17 asked 7:9,11,12,14 15:17 16:2,24 18:10 19:18,19,23 20:12,24 21:2,10 22:6,17 23:13 25:10 34:23 35:3 37:9,12 38:4,17 38:19 43:14 47:5 47:8,14,23 48:4 48:11 53:21 58:18 59:11 60:2 73:8 73:10,21 74:19 79:15,17,25 91:10 92:15,20 99:18 asking 48:3,4 ASLD 65:14 67:19 assertion 55:25 asserts 55:24 assessment 12:12 assigned 40:2 assigning 39:24 41:23 assist 12:12 association 18:7,12 21:14 62:5 associations 18:20 assume 62:18 91:21 assumed 27:5 astounding 41:20 51:18 63:21 Atlanta 1:15 attached 81:19,21 83:9 attack 62:12,17 65:25 attacks 65:22 attempt 34:16 37:1 37:23 attempted 35:11 63:3 93:1 attention 87:5 98:12 attributed 15:7 attributing 40:10	attribution 40:6 AUDIO 2:8 audio/visual 4:22 10:24 author 16:1 27:23 35:9 51:15 71:9 71:14 72:6 73:8 97:16 authored 71:10 authorities 72:3 77:24 authors 19:15 29:13 65:7 66:6 66:10 77:3 99:1 available 4:14 28:19 90:15 aware 6:1 7:8 13:2 42:12 45:5 60:23 a.m 1:6 11:24,24 <hr/> B B 2:5 3:12 14:25 back 20:14 36:11 40:21 42:21 45:22 47:15 48:3 60:19 67:22 68:8 69:13 74:6 75:3 86:18 99:7 100:22 backdrop 72:17 77:2 backfiring 99:20 background 31:4 62:1 77:12 backwards 91:22 bad 50:4 82:7 balances 69:7 based 19:8 38:20 49:21,22 87:16 90:24 basically 91:18 basis 20:3 30:22 33:17,25 38:18 52:16 77:9 BB 97:10 bear 46:3 84:12 bears 15:12 27:2 beginning 6:23	41:13 behalf 10:15 60:8 79:24 86:12,12 behold 76:5 believe 42:7 48:1 55:10 68:20 69:12 96:1 believed 18:23 50:13 believes 39:10 62:11 belong 44:10 bench 11:19 benefit 7:22 Berman 1:10,11 4:7,8,9,19,25 5:3 5:9,12 7:1 9:22 10:7 best 49:18 52:25 better 61:11 63:7 65:15 beyond 95:24 bias 41:20 42:6,6 43:4,6,7 bibliography 92:16 big 60:18,24 63:10 76:21 77:13,14 bigger 98:25 billion 14:24,25 15:1 binder 31:25 35:18 53:2 54:25 55:7,9 58:11,13,21,23 59:2,10 79:10,15 84:2 91:8 99:19 biopsy 83:7 bit 4:21 16:11 17:24 46:2 50:4 52:24 77:13 bizarre 86:5 blame 50:16 blank 27:14,14 36:3,8 blood 27:10 40:5 91:20 board 67:23,24 68:7	body 78:24 91:19 92:17,23 bold 52:21 book 20:1 72:14 73:8,10 bore 6:2 box 84:20 breadth 65:9 break 96:13 Brent 69:17 74:4 86:11 92:15 briefing 6:19 9:1 briefly 19:2 30:3 86:1 bring 81:15 83:15 bringing 85:8,8 Broadway 2:3 brought 68:8 83:13 98:11 Brown 69:16 72:23 74:3,17 78:19 79:6,15,17,25 80:11,24 81:3,13 81:18 82:11 86:10 93:8 98:11 Brown's 98:12,13 98:13 BUENZLE 2:8 bullet 22:8 bunch 62:20 93:20 93:21 burden 78:24 92:17 92:23 BUTLER 2:2,5 <hr/> C C 101:1,1 calculate 91:21,22 calculation 78:24 92:1 call 4:13 7:2,2 8:8 35:5 41:6,7 87:5 called 16:17 26:19 27:1,6,6,9 39:3 45:23 47:1 63:11 67:23 76:5 calls 70:5	capable 15:19 care 76:13 careful 25:14 carefully 38:22 44:2,2 case 6:3,7,9 15:23 15:24 16:4,6,9,13 16:17,18 17:11,11 18:19,19,23 24:4 24:6 26:18,18 27:3 29:4,8 30:1 30:16 32:14,15,23 33:1,3,4,5,15 34:9 34:11,11,24 35:4 35:5,12,12,17 38:13,20 39:1,1 39:21,23 40:11 41:12,16 46:15,16 46:17,19,22 47:2 47:18,21 48:3,9,9 53:23 54:1,16 56:16,21 57:20 58:2,16 60:21,25 61:1 64:25 65:12 65:21 69:11 70:20 75:5 76:25 77:10 78:1,12 80:15 82:5,15,23 83:2,4 84:19 85:17 88:7 88:15,16,16,21,21 88:22 90:12 95:25 99:6,14,24 100:1 100:2 cases 12:3,22 13:20 13:23 14:3,9 15:4 15:7,11,13,14,16 15:23 16:20 18:15 20:20 22:23 23:3 26:7 27:22 28:3,5 28:7,20 29:17,18 29:20 30:7,11,11 30:20 31:1,8,15 31:16 33:21 35:2 35:7,10,15 41:16 42:4 43:11 44:8,9 44:16,19 45:4,12 47:10,25 48:13,22
--	---	---	---	---

48:24 49:3,7,7,21 51:12,16,16,21 53:22,22 54:6,9 57:5,8,8 61:2 62:25 63:2,12,12 63:19,25 64:20 65:9,10 67:9,17 68:11 70:6,8,17 70:18 73:19 76:18 78:11 79:20 80:2 82:18 87:15,16,19 88:18 89:15,19,19 90:25,25 94:11,13 94:20,21 95:20 97:3,7 99:2 categorize 39:1 causal 18:20,25 causality 18:18 38:23,24 causation 12:20,25 13:3,23 14:7 23:25 51:3 87:20 cause 33:13,24 39:24 50:13 61:3 82:19 90:16 caused 13:5 causes 12:7 14:5 15:21 17:6,16,21 causing 22:1 39:2 50:23 caveats 20:14 center 64:24 certain 50:2,8 certainly 5:3 22:13 23:18 50:16 64:15 certainty 23:24 certify 101:5 challenge 77:6,9 95:23 challenged 54:11 challenging 94:21 94:22 chambers 100:22 chance 86:14 chapter 20:1 60:14 73:11 characterizations	58:1 characterize 44:19 charge 71:18 chart 24:11 72:15 75:3 checks 69:7 choose 5:21 chose 66:3 chosen 5:5 Christmas 97:9,11 CHRISTOPHER 1:17 chronic 92:25 cirrhosis 70:15 cite 13:19 14:10,13 25:24 63:23 cited 54:5 claim 6:9 14:5 79:2 claimed 15:6 claims 6:7 classification 30:22 35:6 classified 39:12 classifying 34:24 Clay 1:13 5:24 clean 45:24 46:1,6 48:14,18 clear 71:5 75:15 88:10 clearly 41:20 43:11 clerk 82:7 clinical 17:9 50:11 57:3,19 close 56:23 58:8 71:10 closer 56:5 Coast 6:17 coauthor 13:22 30:2,13 97:15 Cohen 2:2 3:4 10:15,18,19,22 11:2 12:1,2 24:17 25:21 32:5,7,18 33:19,23 34:3,7 39:21 40:20,22 41:1 45:12 52:11 54:13,20 56:16	57:17,25 58:3 60:13 63:13,14,23 64:19 68:10 73:14 73:21 75:1,19 83:12,13 85:19 90:12 94:10 96:15 96:16,20 98:8,10 99:5 100:7,10,16 100:19 coincidentally 88:15 collate 66:16 collateral 53:25 colleagues 19:14 85:2 collect 51:10 collected 15:23 16:3 19:8,11 25:17 42:3 58:14 66:1 collecting 22:23 66:21 collection 15:22 16:17 17:11 25:19 67:4,15 68:4 69:9 COLLOQUY 3:2 Colony 2:6 colors 46:9,9 column 47:1,4 coma 26:10 35:21 comatose 35:24 combination 37:20 combine 92:23 come 20:14 28:5 52:18 70:2 71:23 85:12 93:15 comes 20:2 25:10 35:4 37:18 comment 8:17 27:15 comments 81:18,19 commercially 90:15 commit 37:25 64:1 commitment 11:14 committee 15:3 20:24 21:5 23:12	38:23,24 45:15 62:7 67:7 committees 67:9 committing 63:4 common 41:13,25 76:2,2,8 commonly 43:10 community 19:3 23:1 31:14 57:21 61:16,20,25 62:14 62:15,16 63:17 72:12 78:15 79:8 99:3 company 1:23 50:16 company's 50:15 compare 69:2 complete 5:17 completed 6:25 10:3 completely 22:13 36:3,8 comprised 15:22 compute 41:18 computer 25:5 conceded 17:16 44:7 concern 93:19 concerned 74:5 concluded 33:15 46:15,17,19 100:24 conclusion 50:21 85:13 87:20 conduct 67:11 68:5 69:1 conducted 33:18 67:12 conference 1:7 4:13 7:2 11:23 confidentiality 31:21,22 confirm 16:15 29:16 confirmed 16:14,21 28:1 29:5,21 65:3 76:18,19 83:10	85:15 confirming 93:14 confirms 28:23 conform 43:11 confusing 88:18 connection 50:11 66:24 74:10 consensus 61:15,19 61:21,24 62:11 consider 50:17,18 52:2 73:16 76:15 77:3,4 98:15 considerable 7:6 considered 28:12 57:11 72:3 consist 84:6 consistent 60:6 64:9 83:7 constant 96:7 constitutional 64:5 consumed 20:10 consumers 14:25 contacted 86:8 contain 98:19 context 14:22 59:7 continue 92:4 continued 2:1 continues 92:5 continuing 6:24 contradictory 95:3 contravening 94:5 contributed 83:4 contribution 69:4 control 16:22 17:10 controlled 16:23 controversies 22:4 controversy 22:5 22:10,16 23:17,17 conversation 49:3 conveys 45:25 convinced 57:20 convincing 23:5 coordination 9:14 coordinators 24:18 copies 5:13 9:1,7 10:4 26:1 copy 7:13 26:3 55:5
---	--	--	--	--

62:18,19 73:24 83:22,23 84:3 core 13:3 coroner's 34:19 37:3,4,5 38:17 correct 16:18,20,22 17:1,22 30:23,24 35:7 39:2 43:2 55:13 85:2 101:6 corrected 68:9 correcting 49:4 corrections 87:3 correctly 97:1 correlate 75:20 counsel 16:2 21:1 32:1 52:7 86:10 counter 26:23 country 6:17 county 37:5 couple 28:8 49:15 49:16 64:7 93:18 course 20:4,7 27:14 30:17 34:4 38:14 53:4 54:15 67:14 84:25 95:4,6 court 1:1,23 4:2,18 4:24 5:2,7,11,15 5:23 7:15,25 8:5 8:10,14 9:2,11,12 9:21 10:5,6,11,17 10:21 11:1,12,21 12:1,12 13:1 18:18 25:20 26:5 32:2,4,6,16 33:16 33:22 34:2,6 40:21 45:10 52:9 52:12,15 53:7,9 53:13,14,15,16 54:16 55:1,6,7,11 55:14,19,22 58:21 58:24 59:4 60:23 61:18 66:5 71:3,4 71:25 74:1 77:7 79:12 81:5,16,22 83:25 84:4,16 86:2,24 87:2 88:20 89:8 91:7	91:10 93:23 96:12 96:18 98:7,9,15 99:3,5,9,11,17,25 100:9,12,15,21 courtesy 5:13 10:4 courtroom 70:3 79:7 80:12 81:3 81:11 courts 8:22 77:22 court's 87:5 CR 37:10 created 25:13 credibility 30:20,22 credit 5:7 CRF 30:23 31:19 31:24 32:2 33:8 33:25 34:17 36:2 36:8 37:10 38:21 39:16,23 41:5,8 43:15 49:12,14 CRFs 15:25 24:17 25:3 30:5,15 39:9 44:25 45:4 66:2,7 66:13 criteria 32:20 39:23 40:1,6,10 41:3,22 42:4,23 42:24 43:16,24,25 cued 73:20 current 56:5 currently 7:18 cut 37:22 cuts 5:16 cutting 37:25 <hr/> D D 3:1 daily 56:10,20 81:12 Dallas 24:21 29:10 data 12:24 13:18 16:3,3,13 18:23 19:8,11 24:24 25:3,7,9,14,16,19 28:6,18 34:23 39:22 41:14 42:3 45:23,24 46:1,6	46:13,14 48:14,18 49:6,23,25 50:2,4 50:4,8,18,19,20 51:3,10 52:2,3 53:20 55:24 57:3 57:19 64:8 66:21 67:4,15,23 68:4,7 69:9,9 76:12 77:10 82:10 87:22 96:8 97:1,6 98:3 98:19 database 25:5,9,11 29:14 54:23 56:3 56:3,4,9,10,25 57:1 databases 56:22 date 26:9 36:6 101:13 dated 9:25 Daubert 10:2 12:15 53:14 77:8,8,19 81:9,9 Davern 13:21 29:25 72:5,21 73:11 93:4 Davern's 79:11 David 2:2 10:14 day 12:7 13:14 17:6 17:21 19:5,17 20:11 36:1 46:23 46:23 48:14 53:24 56:2,5,11,23 60:5 64:10 80:11 89:1 days 36:25 41:16 42:1 43:11 46:23 49:15,16 88:23 89:2 day-to-day 6:23 deadlines 7:4 deal 60:24 76:21 deals 59:11 death 34:18 38:16 38:21 debating 72:10 decades 62:11 decide 42:13 77:7 decided 42:22 48:5	49:2 declaration 25:1 29:1 48:19,20 66:20 67:25 73:22 75:25 83:1,10 85:5,18,23,24 86:17,21 87:12 88:8 90:5 93:23 95:13 declarations 44:23 71:3,25 86:23 97:19 declined 98:13 defect 6:8 defend 35:11 defendant 10:13 54:11 57:6 62:2,3 65:4 75:24 95:7 defendants 2:2 5:4 5:21 6:14 8:11 10:16 53:15 64:22 69:15 75:10 77:14 82:14 85:17 89:7 92:10 95:23 defense 6:6 defined 13:13 defining 56:20 definite 97:17 delete 47:2,3 49:2 deleted 48:6 deliver 7:16 demonstrate 91:23 93:6,19 100:4 demonstrates 100:6 demonstrative 4:22 depends 36:16 depose 49:17 deposed 49:18 deposition 6:6,10 7:19,19,20 13:23 16:15 17:4 19:19 20:25 22:7 28:25 29:6 30:4,9 35:3 51:18 58:19 59:3 59:9 68:21 75:14 79:11 87:4 92:14	98:13,21 depositions 5:17 6:16 9:6 10:2 11:4 49:13 97:21 describe 14:14 16:13 82:23 87:20 92:2 described 16:8 27:21 48:23 63:11 65:1 67:24 82:25 83:7 88:8 95:2 describes 27:22 45:25 73:23 describing 87:7,19 description 3:13 89:5 descriptive 87:22 design 6:8 12:18 16:15 18:5,17 50:24,25 designations 6:6 designed 16:23 17:2,4,14,19 24:7 24:8 29:16 51:2 62:20,21 87:1 designing 50:22 detail 33:2 details 34:10 determine 92:24 determining 56:18 develop 57:12 60:4 developed 59:21 76:3 diagnosis 84:14,18 died 34:17,21 differed 28:14 difference 77:17 87:17 89:16 different 5:6,6 7:23 24:9,19 27:16 33:8 50:12 56:22 88:18 differently 17:24 difficult 64:12 82:13 94:9,10 95:9 difficulty 56:20
--	---	--	---	--

64:16 88:2	12:11	39:10,10,22 40:9	69:21	26:10,13
digits 31:18	doing 8:24 47:20	40:17 42:19 43:3	drugs 69:25	encourages 86:6
dime 71:12,16,20	52:22 62:9,10	43:9,12,14,15,17	drug-induced 72:5	ends 88:16,17
directed 34:25	68:15	43:18,19 44:7,17	72:20 73:5,11	enroll 24:8 79:19
directions 7:24	dose 13:10,11,13	44:18,24 45:4,14	83:7	enrolled 26:12
directly 69:6	15:8 18:13 21:7	46:1,5,13 47:5,8	due 6:11,12,20	36:22 84:9
disagree 22:18,20	23:13 27:4 32:14	47:14 48:5,18,19	31:21 70:12,19	enrollee 42:15
disagreements	32:15,17,19,24	48:23 49:13,14,14	81:1 85:11	entered 25:4,7
22:18	36:7,9 38:3 39:4,8	49:25 50:10,14,25	duration 36:8	entitled 5:19
disclose 42:5 65:7	46:23 47:17 49:8	51:17,19 52:1	d-CON 34:15,15	entry 25:8
disclosed 31:8,21	54:15 55:17 56:6	58:6,10,18 59:11	35:4,5,12 36:24	epidemiological
discovered 15:7	56:6,10,21 57:10	60:14 64:24 65:3	46:16 47:3	17:10 51:5
31:7	61:5,5,10 65:3,16	66:12,13,14,19	D.C 1:18	epidemiology
discuss 15:13,13	70:20 75:18,20	67:8,25 68:20		57:19
30:6 45:8 52:7	76:19 80:21 82:20	69:2,16,17,17	E	equal 72:13 89:20
69:18 76:20 85:25	83:10 85:12,15	71:17 72:2,5,21	E 3:1,12 101:1	equipment 10:18
94:10 98:21	87:8 90:1,17	72:21,21,22,23,23	eager 41:16 42:4	errata 49:5
discussed 22:11	91:12 92:24 93:7	73:8,11 74:4,4,17	earlier 27:21 29:7	error 39:13,14
41:5 67:10,16,18	93:14 96:24,24,25	74:17 75:6,6,14	50:7 82:3	44:12,15 51:19,20
discussing 59:12,18	97:7 98:4 99:22	75:25,25 76:16,17	early 41:16 42:1	ESQUIRE 1:10,13
60:21	100:5,7	76:19 78:6,19,20	43:11 61:9 65:23	1:17 2:2,5
discussion 4:4 7:6	doses 13:4 14:12,24	79:6,11,15,17,24	East 1:15 6:17	ESR 100:23
35:15 63:24	17:6,16,21 19:16	79:25 80:11,24	EASTERN 1:2	essentially 11:7
disease 21:15 62:6	28:19 29:16 30:6	81:3,13,18 82:11	Edition 25:25	15:5 16:19
69:5 70:15 72:5	37:19 50:24 56:5	82:15,17,24,25	editors 31:10	establish 12:19
73:5,9,11 83:8	56:23 76:4	83:3,3,9,10,23	effect 68:6	13:23 18:20 54:10
89:12	dosing 26:7 30:21	84:23 85:2,4,7,9	effective 20:10	97:2,6 98:4
display 4:22	30:23 36:17 46:22	85:14,18,23 86:9	efficient 11:8	established 18:24
displayed 5:10	46:24 51:11 63:18	86:9,12,13 87:4	eh 50:4	establishes 98:5
dispute 38:18 51:9	64:11,17,21,22	88:8,15 91:9	EHRs 56:2,9	establishing 15:20
95:11	88:3,6 91:23	92:10,10,13,15,20	either 20:3 40:2	estimated 92:17,23
DISTRICT 1:1,2,8	92:25 94:20,22	93:3,3,4,8,9 94:6	49:20 61:4	ETOH 26:16
divided 17:6,21	95:8,15	94:12,13,14,18	elected 21:21,21	evaluate 39:7
diving 57:24	Dr 13:18,21 16:1	95:11,12,12 97:3	electronic 1:21	evaluated 15:14
doctor 34:20 37:7	16:14,21 17:3,16	97:4,15,16 98:11	101:7	30:5
38:7 44:14 57:12	17:19,22,23 18:6	98:12,13,13,18	elevated 57:4	evaluation 48:21
76:24 81:12 84:17	19:13,14,18 20:5	draft 66:17	email 45:24 80:11	event 4:3
doctors 36:21 63:8	20:12,16,22 21:4	drafted 73:17	81:17,25	eventually 47:19
71:22 94:24	21:8,10,13 23:5,8	86:22,22	emails 79:11 80:5	everybody 22:2
document 41:23	23:11,15,18 24:25	drafts 30:14 86:18	98:12,14	93:4 94:6
43:16,17 50:1	25:13,21,23 27:23	drinking 34:13	emphasize 65:11	evidence 6:12 11:9
54:19 55:1	27:24 28:1,4,16	35:25	71:21 78:6	12:11,13,15,25
documentation	28:25 29:12,25,25	drive 7:15 8:3	emphasized 25:13	13:2 14:8 22:14
41:9	30:8,8,19 31:14	Drs 18:22 22:24	employ 79:20 81:10	31:8 32:23 52:18
documented 41:8	32:14 33:3,14	74:3 86:10	93:10	56:17 57:15,18
42:21,25 43:2,10	34:23 35:3,9,11	drug 19:17,22 21:6	employed 69:8	65:13 73:17 96:9
documents 8:21	35:12 37:2,9 39:6	50:12 58:7 65:18	encephalopathy	98:15

exactly 17:23 49:25 86:7,20 89:1,21	explained 23:19 40:9	familiar 55:1	first 4:10 12:9,18 15:18 18:19 25:24	format 5:6
examine 49:12,13	explanation 49:5	farce 79:13	31:14,17,18 35:9	forms 15:23,25 16:4,9,11 24:6,22
examining 51:8	explore 79:3	fashion 41:22 74:16	37:9 41:10 52:14	25:4 29:4,8 38:13
example 8:25 35:14 51:25 54:18,24	exposed 90:9	fast 6:13 7:24	54:6 57:14 62:23	68:25 78:13 82:5
82:12 92:13	extensively 66:20	father 36:20 37:24	66:17 70:25 74:14	84:6,7
examples 51:13 79:9	extent 9:8,11	faulty 50:17	77:18 80:22 85:17	formula 91:18,18 93:5,17
exclude 34:1	extra 5:7	favor 22:14	FISHBEIN 1:11	forth 60:1 86:18
excluded 46:10,16 46:18,20 47:7,9	eye 97:12	faxed 24:21	fits 65:20 87:22 89:1 95:19	forthcoming 15:16
47:13 48:21,25	F	FDA 14:1 15:3 20:23 21:3,4,11	five 49:6 68:19 88:23 89:2	forum 60:10
49:6,21 99:1	F 1:7 56:9 67:5 101:1	31:9 44:21,25	five-year 80:1	forward 40:24,25 40:25 58:9 71:23
excreted 92:6	fact 28:25 29:21 38:15 44:21 45:21	45:5,14,17 49:11	Flamm 64:24 65:3 69:17 72:23 73:8	93:15
excuse 14:20 29:25 60:25	54:6 57:17 58:11	51:21 53:20 54:18	74:4,17 76:16,19	found 40:16 41:19 45:21 93:16
exhibit 28:24,24 82:14 83:9 84:1	61:22 68:20 70:23	54:22,25 55:3	78:20 82:17,24	Foundation 62:6
exhibits 5:13 53:4	73:7 74:13 76:11	56:3,15,19,19,24	83:10 85:2,7,9,14	four 26:11,11 33:9 33:11 37:7 38:15
exist 76:22	76:15 87:14	60:10 62:4,4,6	86:10 88:15 92:13	44:8,16,18,18 70:3,4
existing 22:14	factors 26:15	65:13,14 77:25	92:20 93:9	fourth 55:10
exists 77:20	failed 26:21 73:16 76:15,20	78:4,7,18 93:13	Flamm's 82:15 83:3,3,23 84:23	frame 11:4
expect 42:24 95:9	failure 6:7,15,19 7:7 12:4,8 13:5	93:16	44:9,17 49:24	frankly 41:19 59:6 59:7 63:20
expected 74:17 94:23,24	14:6,11,16 18:8	features 76:3	50:2,18,19 51:12	freely 95:13
expects 43:3,5,12	33:13 51:8 54:7	federal 12:14 50:6 78:4	51:24 52:2 79:3	Friday 85:17,24 87:1 94:13
expedited 7:11 8:2 52:16	56:4 57:13 59:21	federally 59:20	flaws 12:23 39:6 68:23	friendly 22:18
experience 60:6	59:24 60:4,7,9,22	feel 5:18	focus 21:22 27:17 66:4 70:1 83:18	frivolous 87:1
expert 12:6 14:7 30:1 74:3,15 77:5	61:4 62:7,13,22	fell 28:20	83:20	front 18:1
80:4,12 95:24	63:2 65:2 66:22	female 34:13 36:24	focused 55:2 66:3 69:19 89:14	fulfill 39:23
experts 13:7,19,21 14:10,14 44:24	67:2,11 68:8,13	Ferry 1:15	follow 5:15 42:18	full 6:2
64:23 69:16,19	69:20,23,24 70:8	fewer 70:18	followed 28:17	fund 71:17
72:18 73:3,5,12	70:10,12,18 71:8	field 39:14 73:5	following 21:3 58:18 71:3	funded 59:20 78:5
73:16 75:5,6,10	71:11,16,18 72:20	fields 73:3	follows 12:17	furnished 9:9
75:23 76:11,12	73:1,6 74:10,18	figure 8:8	follow-up 15:11	further 70:21 82:21
79:3 81:10 89:25	76:4,25 77:3,15	filed 10:2 79:16 80:12 85:17,23,24	footnote 56:8	G
90:20 91:6,16	78:21 79:18,19,20	86:8,12 87:1	foregoing 101:6	GA 1:15
92:9,10 94:7	79:25 80:2,8,9,13	filing 60:21	forget 70:4	garbage 25:15,15
95:23 97:3,5	80:15,17,20,25	filings 10:4	form 24:4 26:19 27:3,14,16 30:18	gatekeeping 12:14
98:25	81:1,5 82:4 83:6	fill 84:20	35:17 37:5,8	general 19:21,22
expert's 97:21	85:10 87:21 88:13	filled 24:17 25:4 84:8	83:14,18,20 84:7	generally 9:20
explain 37:17 46:3 76:3,9,9 98:14	89:6,11,20 90:3	final 31:1 84:14,18	84:8,15 85:21	generic 36:5 60:24 61:13
	90:16,18 91:1,2	finally 13:24 26:25 27:8 38:19 50:10		genetic 75:24 76:1
	92:3 93:10 98:3	98:17,23		
	failures 70:17	find 40:11 78:1 84:13 85:20 94:25		
	fairly 65:8	Finlay 22:16		
	falls 30:20 48:9			

76:2,8 98:19 GEREL 1:17 getting 25:14 64:16 give 4:12,15 8:23 21:18 26:2 62:19 79:8 82:12 83:23 84:11 87:19 94:25 given 5:1 9:19 34:23 36:20 41:11 75:11 88:24 91:23 gives 92:6 giving 61:11 64:16 81:24 88:2,3,13 global 59:19 go 17:24 33:1 34:10 40:21 42:21 47:15 48:3 53:25 56:14 56:14 58:11,13 59:10 60:10,18 63:22 69:13 72:8 72:16,24 74:6 75:3 85:4 89:23 94:12,14 99:23 God 97:21 goes 25:15 57:12 64:6 77:10 going 5:10 6:2,13 7:23 8:18 10:12 10:15 15:24 20:14 24:4 27:5 30:2 31:23 32:7 34:9 34:10 40:14 45:10 45:15 46:12 47:11 48:10 52:25 53:21 58:12 74:25 75:18 77:13 79:6,8 80:18 82:12 95:9 95:21 96:13,23 97:10,11 good 5:22,23 8:14 8:15 25:14,16 41:15 gotten 88:25 government 78:4 grades 26:11 Grail 93:17 grams 12:6 13:14	14:5 17:6,21 18:9 19:5,16 20:11 23:6,10 28:9,21 32:20,20,21 35:25 36:1,11 40:3 48:14 56:1,5,11 56:23 57:3,23 58:8,10,18,23 59:24,25,25 60:5 61:4 64:10 76:6 76:25 83:11 87:8 88:23 89:1,6,20 98:19 grant 43:5 67:1 71:9,19 graphics 100:13 gray 46:10,10,17 46:18 graying 47:6 great 33:2 green 46:19 47:18 grotesque 45:7 group 6:16,20 7:7 12:4 14:1 15:5 16:22 17:10 47:25 54:19,25 55:4,12 56:4,15,19 57:8 59:21 60:9,22 62:4,8,13 65:14 66:23 67:2,11 68:8,13 69:23,24 71:8,18 74:19 76:7 77:15 78:21 79:18,19,25 80:2 80:9,13,20 81:5 87:22 88:7,13 90:19 93:10 98:3 groups 80:8 Group's 82:4 guess 21:8 guilty 10:19,22 guise 94:2 gun 90:15 97:11,13 97:21,22 99:20 guys 81:6 <hr/> H <hr/>	H 3:12 half 60:20 63:3,6 91:14,21 92:23 96:5 hand 32:2 53:8 handful 32:12,13 89:14 handle 96:25 handling 96:23 hands 7:20 handy 40:8 hand-up 5:14 Hang 39:17 74:1 happen 68:24 happened 29:3 65:24 69:11 80:3 happens 22:2 90:11 hard 26:3 harm 63:4 Hayes 61:1 hazardous 64:10 head-down 25:7 Health 53:19 66:25 67:6 68:17 69:10 78:9 hear 52:15 53:19 75:1,19 77:10 heard 21:16 31:13 72:17 73:13 89:19 97:22 hearing 7:3,8,11,16 77:8 hearsay 98:16 heavily 61:14 heavy 36:25 help 29:16 76:9 85:21 helped 33:20 helpful 9:16 HENRY 1:14 hepatic 26:10,13 56:2 hepatitic 35:21 hepatitis 70:14 73:3 hepatologist 13:17 Hepatology 31:11	51:22 53:18 78:19 hepatotoxicity 20:6 57:4 herbs 26:22 hey 49:5 high 75:20,20 92:6 92:7 97:6 higher 77:21,22 78:3 highest 77:24 highlight 26:20 highlighted 28:10 highlights 39:6 highly 51:12 histories 26:7 30:21 63:15 95:1 history 30:23 36:20 37:24 63:18 64:17 64:21,22 88:3,3 91:23 94:20,22 95:2,8,15 hoc 90:25 holder 71:9 Holy 93:16 honor 4:8 5:18,22 6:1,20 7:8 8:13,23 9:8,18,23 10:14 10:20 11:3 12:2 13:12,24 20:22 21:18 25:24 30:1 31:5 32:22 33:2 36:3 39:5 41:19 42:5 45:7 48:17 50:21 52:5 53:2 55:21 63:20 66:9 66:19 69:7 73:20 73:25 80:23 83:24 84:13 90:23 93:23 93:24 94:8 96:3 96:20 97:8 98:23 99:14 100:8,10 HONORABLE 1:7 Honor's 5:12 9:15 hooley 93:21 hope 12:12 hospital 27:12 40:5 57:9 76:23 88:25	89:2 100:2 hospitalization 41:15 88:22 hour 11:15 housekeeping 100:10 human 60:3 hundred 80:7 hurry 47:11 48:10 Hy 21:18 hypothesis 50:22 hypothetical 92:1 <hr/> I <hr/> idea 5:10 identical 54:22 identified 15:14 16:4 28:5 68:6 identify 12:22 23:3 identifying 88:14 idiopathic 84:22 ignored 34:3 ignores 60:15 illustrate 58:2,4 62:13 73:7 99:23 illustrates 79:13 immediately 35:11 importance 73:23 important 14:15 18:17 25:6 26:17 29:2 43:1 48:12 48:16 49:24 52:16 52:19 57:16 61:13 63:5,10 66:18 72:10 73:17 74:24 77:20 83:14,17 86:4 90:22 92:8 95:19 importantly 54:13 69:17 78:19 80:6 inappropriately 92:7 inattention 79:19 include 95:12 included 43:21 44:5 80:6 82:18 90:13
---	--	---	---	--

including 26:22 57:6 61:10 64:21 67:3,4,4 73:18	20:20 29:23 36:24 39:12 48:13 56:1 93:20 98:20	75:8 79:22 85:17 85:19 87:14 89:24 91:14 93:13 96:6 99:19,20	keep 9:18 29:2 keeps 40:22 Kemp 10:1,24 key 26:4 kind 90:4 kinds 68:25 knew 20:20 37:14 38:14 know 5:16,19 7:10 19:21 23:5,8,11 23:15 34:4 36:6,7 36:7 38:8,10,11 43:17,18 45:1 51:21,22,23,23 63:17 74:7,8,9 78:10,11 80:13,14 80:15,16 81:6,25 82:1 83:16 84:25 85:3,3,14 87:17 93:16 96:22 98:6 100:1 knowledge 61:7 75:12 known 5:4 16:8 17:11 21:15,19 33:12 knows 54:17 Kort 76:6	43:14,17,19 44:7 44:18 45:16,18,19 45:22 46:5,7,14 47:5,8,14,24 48:6 48:18,23 49:4,14 50:25 51:1,19 52:1 54:21 59:13 59:18 62:17 66:2 66:14 71:10,13,14 72:6,22 75:6 87:8 92:10 94:13,14 95:12 96:10 97:4 97:15 Lastly 9:13 late 6:4 LAURA 2:8 Laurence 1:10 4:8 law 1:10 82:7 86:6 LAWRENCE 1:7 lawyers 86:6,9,18 86:23 lead 7:18 16:1 51:14,14 71:14 learn 75:5 85:12 learned 25:8 48:24 49:19 83:8 97:20 Lee 17:16,22 18:6 18:22 19:13,18 20:22 21:4,8,10 21:13 22:24 23:5 23:11,15,18 24:25 25:13,21,23 27:24 28:25 29:12 30:8 30:19 31:14 32:14 33:3,15 34:23 35:3,12 39:10,22 40:7,9,17 43:15 43:18 44:17,24 45:4,14 46:1 48:5 48:19 49:14 50:10 50:14,25 58:6,10 58:18 59:11 60:14 66:12 67:25 69:2 71:6 72:21 73:22 75:6,14 76:17 79:24 85:18,23,24 86:9,9,13 87:4
incorrect 38:2 91:24 increase 55:17 61:12 independent 77:23 indeterminate 84:22 indicate 47:6,16 90:1 97:17 indicated 52:23 54:13,20 56:24 57:6 58:5,6,10 78:7 88:22 90:1,3 92:13 indicates 56:9 57:3 84:18,19 88:1 90:6 91:3 indicating 34:20 indicia 77:20 91:3 indiscernible 5:8 7:19 8:4,4 9:16 24:15 40:18,19,24 47:3 84:15 97:14 100:17,20 individual 42:22 57:5 68:11 individually 42:17 94:15 individuals 56:7 induced 59:23 indulgence 99:15 inevitably 68:24 information 4:16 8:21 9:10 15:15 15:17 27:7 30:16 30:18 31:20 37:11 37:14 39:8 48:12 64:11 66:14 68:3 86:16,16 88:14 95:4 informed 41:24 ingestion 14:12 15:8,20 17:6,21 18:2,9,13,25 19:4	ingestions 22:4,8 ingredient 15:1 initial 80:24 initially 38:10 injury 13:5 22:2 33:13 50:14 56:2 64:8 72:20 Institute 53:19 Institutes 66:25 67:6 68:16 69:10 78:8 institution 34:19 36:16 65:1 88:17 instructions 61:11 65:15 intend 59:6 intended 59:6 intent 5:4 interesting 83:13 83:19 interestingly 73:9 75:22 internal 67:24 investigate 86:7 investigator 36:21 36:22 41:7 51:14 71:7,7,13 72:6 79:23 investigators 24:19 30:8 32:13 33:7 67:14 68:1 90:19 invite 97:25 invited 20:23 21:17 21:18 involved 11:4 54:16 66:12 68:14 82:2 involves 6:7 34:12 91:15 involving 50:12 92:12 IN-PERSON 1:7 issue 6:20 7:20 42:11 53:25 58:17 60:25 65:22 75:8	issues 6:2,24 52:6 53:25 54:5 58:16 63:17 67:10,15 72:10 80:21,22 85:16 <hr/> J Jackson 6:8 13:15 January 9:25 29:1 69:14 70:3 82:8 82:17 86:22 89:8 90:23 Jersey 4:6,11,16 6:20,22 8:19,24 13:16 jive 78:14 job 66:14 Johnson 4:14 7:3 7:17 8:25 9:3,14 9:18 10:23 52:20 61:18,23 Johnson's 8:6 9:24 Jones 2:5 8:12,13 8:15,15 10:14 11:19 100:21 Journal 31:10 41:25 53:18 78:19 Judge 1:8 4:13 7:2 7:3,16 8:6,25 9:3 9:14,18,23 10:23 11:18 52:14,20 61:18,23 Judi 2:9 101:4,13 jump 53:1 jumping 40:22 June 45:14,18 jury 6:11,25 77:11 89:18,18 96:9 <hr/> K K 1:18 Kaplowitz 13:18 72:2,21 93:3	labs 41:18 lack 23:23,24 43:4 43:6,7 largely 90:19 larger 57:18,18 largest 60:6 Larson 12:5,19,22 13:8,19 14:2 15:4 15:10 16:1,14,21 17:3,14,19,19,23 18:22,24 19:7 20:5,7,8,12,16 22:25 23:4,8 24:3 24:20 27:17,23 28:1,4,16 30:8 33:18 35:9,11 37:2,9 39:6,10	

90:5 91:9 92:10 93:3 94:6,18 95:12 97:3,16 98:18 Lee's 43:9 46:13 51:17 75:25 82:25 83:9 85:4 88:8 left 87:10 let's 17:13,24 19:2 35:17 39:16 40:11 42:21 48:2 52:9 85:16 91:7,14 94:15 level 27:10,10 36:13,14,16,18 40:4 92:6,7 100:4 levels 74:20,25 75:1 97:23 LEVIN 1:10 LIABILITY 1:5 life 81:12 91:14,21 92:23 limb 95:24 limine 9:15 limit 28:13 limited 4:2 line 30:9,10 59:12 60:3 72:18 lines 30:12 65:13 98:21 lining 6:10 list 6:12 36:2 listed 36:4 70:22 82:20 literature 57:7 59:22 60:15 78:14 87:24 95:14 litigation 1:6 9:20 14:4 31:7 69:19 77:23 85:9 90:21 little 16:11 17:24 46:2 50:4 52:24 64:10 65:6 77:13 84:20 liver 6:15,19 7:7 12:4,7 13:5,5 14:6 14:11,15 18:8	21:15 22:1 33:13 33:13 50:13 51:8 54:7 56:4 57:13 59:21,23 60:4,7,9 60:22 61:4 62:6,6 62:7,13,22 63:1 64:8 65:2 66:22 67:2,11 68:8,13 69:20,23,24 70:8 70:10,12,15,17,18 71:8,11,16,18 72:5,20,20,25 73:4,5,6,9,11 74:10,18 76:4,24 77:3,15 78:20 79:17,24 80:2,8,8 80:13,15,17,20,25 81:1,4 82:4 83:6,8 85:10 87:21 88:13 89:5,11,11,20 90:3,16,18 91:1,2 92:3,5 93:10 98:2 LLP 1:14,17 2:2,5 lo 76:5 location 38:9 long 54:16 65:24 90:9 look 8:3 16:10 19:2 24:4 28:13 34:9 35:17,18 39:16 55:15 56:8 62:20 62:21 66:7,9 69:1 74:7 80:14 87:2 91:20 97:25 looked 28:6,17,18 29:3 41:15 54:19 looking 28:22 45:22 46:13 52:21 66:12 74:15 looks 21:11 81:17 loop 9:19 Lortab 36:5 Los 37:6 lot 7:23 15:24 21:16 44:20 49:17 63:14 65:4 68:10 69:25 76:13 95:7	98:11 low 13:10,11,13 14:12 17:16 18:13 27:4 29:16 30:21 32:14,17 47:17 49:8 50:24 54:15 65:3 70:20 76:4 97:5,7 lowered 55:17 65:16 lowering 61:10 low-dose 12:3,22 12:24 13:20 14:3 15:4,20 18:2,15 18:25 20:20 22:4 22:8,23 29:20,22 30:5,7,16 31:16 33:4 39:1,12 44:9 44:19 48:13,24 49:7 51:9,16 54:7 63:12 67:17 73:19 76:18 78:11 82:23 87:19,21 93:19 97:2 L.A 34:19 38:17 <hr/> M <hr/> M 2:2 Macrobid 33:8,11 90:11 main 4:3 29:9,19 38:8 major 95:10 making 12:12 37:23 manner 5:6,20 Manual 16:8 18:3 25:12,22,23 29:19 29:22 Manuals 67:3 manufacturer 55:24 manuscript 30:14 march 80:10 81:17 82:9,9 93:22 marching 70:2 81:5 89:8 90:23	margin 54:8,10 55:18 57:22 61:8 61:12 64:9 65:17 93:20 mark 22:5,9 marked 3:13,14 28:24 Market 1:24 MARKETING 1:4 math 37:21 Matt 40:7 matter 52:17 68:12 100:11 101:8 maximum 19:16 32:19 36:18 56:6 McNeil 15:16 56:16 57:21 61:6,20,25 62:11 66:1 74:19 85:23 86:12,20 90:20 93:15 McNeil's 65:22 73:16 76:11 80:4 89:25 91:6,17 MDL 9:2 13:3,22 30:2 mean 47:20 75:9 82:6 87:7 95:3,5 95:15 96:8 means 22:17 25:8 26:13 40:1 46:10 meant 26:20 47:15 38:8 measure 91:19 99:22 100:7 measures 61:9 99:21 100:6 median 56:10,11 87:7,7 medical 13:3 22:25 34:19 46:12 57:7 57:21 59:22 60:14 61:16,19,24 62:14 63:15,16 64:24 72:11 78:14,15 79:7 84:17 88:3 95:14 medication 33:10 36:2 64:4	medications 26:19 26:21 32:10 medicine 18:21 22:17 39:15 44:13 44:15 meds 26:23 meet 7:4 43:25 86:14 meeting 21:16 23:16 67:13 meetings 67:8 meets 81:13 member 38:24 members 69:23 74:18 memo 82:7,8 mental 26:13 35:22 mention 29:23 30:3 48:18,19,20 mentioned 7:1 9:17 24:3 27:18 70:13 70:14 met 86:14 methodologically 35:15 methodology 12:21 12:24 23:2 24:2 31:2 39:7 41:21 44:9,22 66:6,19 68:12 69:8 70:5 78:10 81:11 82:5 98:24 methods 49:22,22 51:9 meticulously 68:22 midpoint 56:12 MID-ATLANTIC 1:23 mid-February 86:15 mid-2000s 61:9 79:18 milligrams 36:11 37:14,16 38:1 milliliter 97:24 Milling 1:13,14 4:12 5:22,23,24
--	---	--	--	--

5:24 8:1,6,17 9:13 52:20 mind 29:2 32:1 minimum 49:20 minute 60:19 minutes 34:11 52:6 96:17,19 misfired 97:13,22 97:23 missing 24:24 68:25 moment 11:20 22:12 24:4 26:2 27:18 69:18 72:16 79:1 84:2,12 100:22 monitoring 67:23 68:7 monthly 20:3 67:7 months 26:22 41:10 71:2 78:17 80:11 82:3 morning 5:22,23 8:14,15 mother 97:10 motion 6:15 10:24 82:14 85:23 86:8 86:11,25 96:2 motions 7:21 9:15 10:1 60:21 mountain 11:8 movie 96:22 97:9 moving 18:15 multiple 6:2 58:9 multiply 37:19 mushrooms 26:22	nation's 72:3 NE 1:15 near 57:23 61:4 necessary 77:19 need 26:2 45:8 72:9 72:18 needs 73:25 never 27:3,4 29:3,5 30:5,5 31:8,13 38:7 41:24 43:10 44:25 45:3,4,6 49:9,10,11 76:11 79:3 92:11 93:1,9 93:22,25 95:11 Nevertheless 79:21 new 2:3 4:6,11,16 6:20,22 8:19,24 13:16 74:7 80:1 82:8 NH 71:18 NIH 31:9 42:10 43:3,4,12 44:21 45:1,6 49:11 50:1 50:1,3,5,6 51:22 67:20,25 71:9,17 77:25 78:18 NIH-funded 62:23 nitrofurantoin 33:10 non-litigation 90:20 non-party 42:9 49:16 normal 100:5 note 34:18 37:4 60:16 71:21 92:8 noted 28:6 34:16 61:19 notice 5:1,19 71:24 84:5 noting 27:3 number 3:13 21:23 31:19,24 36:14 55:3,3 58:23 61:3 61:6 70:7,11,16 82:14 85:22 87:14 88:7,16,16 89:4	89:23 92:1 99:24 numbers 31:24 93:18 numerous 61:23 NW 1:18 NY 2:3	Operation 67:3 Operations 16:9 18:3 25:12,22,23 29:19,22 OPERATOR 2:8 100:23 opine 21:6 opinion 12:6,6 14:7 59:22 87:12 opinions 60:8 72:12 opportunities 60:11 opposition 85:25 oral 7:22 order 5:12 7:5 9:24 9:24,25 26:12 OTC 26:23 ought 60:16 70:24 95:25 outcome 84:8 outside 28:20 61:21 81:3 outstanding 35:14 overdose 21:25,25 27:2,5,6,19 32:11 34:14,21 36:10,24 37:6 38:5,8,15 46:22 47:17,22 64:3 97:18 98:5 overdoses 22:1 27:20 over-the-counter 15:2	pages 73:25 paid 71:12,16,19 pain 63:8 64:4 paper 12:5,19 13:8 13:13,20,22 14:2 16:2,4 17:14,14 18:6 19:7,15 20:19 24:20 27:19 27:24 28:1 29:4,8 30:2 31:3 33:18 35:10,10,14 38:12 43:22 44:5,5,11 45:20 51:15 59:13 59:19 63:24 65:6 66:9,9,11 72:7 80:18 87:22 95:18 95:19 99:1 papers 44:23 61:22 79:16 98:18,22,22 paperwork 79:20 paper's 96:10 paragraph 13:7,9 15:10,12 23:4 27:20 31:3 32:21 54:21 55:2,3 87:6 87:9 parcel 13:2 Park 2:6 part 12:14 13:2 24:10 30:15 37:3 41:8 42:17 45:23 47:25 57:17 61:25 63:5,9 66:11 68:1 78:20 83:15,20 participant 70:22 participate 4:15 79:25 participated 70:23 particular 55:2 62:17 parties 6:2,22 52:17 96:8 parts 27:16 65:6 83:14,17 party 10:19 passed 53:17 68:19 passeded 53:17
<hr/> N N 3:1 101:1 name 80:18 81:4 nanomoles 97:17 97:24 narrow 54:8 57:22 61:7 64:9 National 1:23 53:19 66:25 67:6 68:16 69:10 78:8	<hr/> O O 101:1 objection 5:20 10:25 18:4 objections 31:6 observation 89:21 observations 14:18 18:16 57:19 obviously 32:13 44:17 51:12 52:16 occur 56:22 59:24 59:25,25 occurred 97:7 October 13:16 odds 16:25 offer 18:16 offered 98:12 office 10:15 34:19 37:4,5 38:17 officer 42:10 OFFICES 1:10 official 71:17 oh 37:3 40:20 41:5 75:19 97:21,21 98:4 okay 4:18 7:25 8:5 9:12 10:6,11,21 11:1 37:12 45:3 45:20 50:4,8 55:23 81:22 85:22 86:2 91:8 99:8,17 100:15 old 96:22 Olsen 2:9 101:4,13 Once 25:2 once-a-year 67:13 ones 79:12 onset 26:9 64:7 on-goings 4:17 Oops 98:5	<hr/> P PA 1:4,12,24 Paces 1:15 packed 4:3 page 3:1 24:7 25:25 27:21 30:9,12 55:3,14,15,16 56:14 58:19,22 59:11 63:23,24 73:23 83:1,1 90:6 91:9 92:14,21 98:20		

patient 24:11 35:21 36:3,23 43:19,20 43:21 44:3,4,4 64:25 68:4 75:18 76:5,22 82:15,16 82:19 84:8,10,14 84:19,20 85:5,6 88:13,23,24 90:9 90:11 91:21,24 92:3,24 100:3,3,5	personally 65:3 person's 91:19 perspective 8:12 ph 6:3,7 22:16 53:9 60:25 61:1 69:17 74:4 76:6 86:11 92:15 phenomenon 87:21 92:2 Philadelphia 1:4,12 1:24 Phone 24:13 phrased 30:24 physician 24:22,23 physicians 22:20 picking 65:6 picture 60:18,24 63:11 77:14,14 pieces 59:8 pills 37:22,25 pinned 21:9 23:14 place 71:1 places 33:9,11 38:16 plaintiff 5:25 13:19 14:7 plaintiffs 1:10 4:9 4:21 7:10 9:4 13:1,5,6,17,25 14:10 16:2 21:1 30:1 31:6,25 42:8 44:20 52:8 61:14 75:5 92:9 96:25 98:24 plan 7:19 45:19 played 79:7 please 39:17 plug 93:18 point 4:19 16:11 21:4,5 22:8 48:17 50:1,3,5,9 54:24 56:15 57:2 58:2,3 73:7 74:18 75:23 77:18 78:16 81:15 86:20 87:18 90:22 93:8,12 96:3 99:13,23	pointed 52:20 76:17 pointing 19:7 points 4:10 poison 34:16 poisoning 47:3 polymorphism 76:8 98:18 polymorphisms 75:24 poor 25:19 portion 85:20 portions 33:6 pose 12:16 posing 12:9 positive 85:14 possibly 85:10 96:6 post 90:24 post-study 91:5 potentially 39:3 PowerPoint 5:8 52:24 practical 52:17 practice 41:13 42:1 44:15 practices 1:5 67:3 precise 32:14 64:11 predetermined 42:3 preface 19:6 21:21 59:14 prefix 88:11 preliminarily 16:12 preliminary 14:17 prepare 32:25 33:1 53:2 prepared 5:14 32:1 presence 73:18 75:15 85:6 91:11 present 32:23 38:20 94:2 presentation 4:23 5:20 11:7 21:14 21:18,19,20,22,24 21:24 52:25 presentations 5:5	presented 10:23 34:22 53:20 67:10 presently 18:18 presents 52:8 56:2 56:6 91:20 prespecified 40:10 presumably 46:7 presume 77:22 pretrials 6:24 pretty 8:6 32:16 53:13 previous 41:15 previously 9:23 76:21 primary 27:23 75:7 97:16 principal 13:17 51:14 71:7 principle 18:21 52:3 printed 100:14 prior 23:19 36:25 77:23 78:8,9 private 71:6 probably 49:10 81:1 problem 21:25 40:15 46:22 65:7 65:18 66:5 82:3 91:25 98:23,25 problems 50:8 68:3 procedurally 66:1 procedures 66:21 68:17,18 proceeded 35:22 proceeding 23:20 31:5 79:14 82:2 100:24 proceedings 1:21 101:7 process 48:21 66:16 79:2,4 produced 1:22 11:9 51:18 69:15 79:11 product 36:4 61:11 products 1:5 15:2 Professional 101:5	program 42:10 project 25:18 45:24 46:1 48:18 proof 23:23 proofs 96:9 proper 79:20 properly 43:20,21 proposition 54:4 63:21 protocol 16:8 17:25 29:15,17,19,23,24 42:17,18 50:3,5 prove 13:6 22:13 23:21 proven 93:1,1 provide 5:13 41:9 71:24 94:17 provided 9:4,15,23 10:1,3 27:15 44:25 64:22,25 66:15 67:20 68:3 69:10 71:3 72:1 72:14 75:4 86:21 providing 9:5 public 49:9 59:15 60:10 publically 31:14 publication 33:4 80:6 publications 72:19 75:4 public's 87:24 publish 19:10 45:16 49:23 published 12:4 14:13,23 15:10,11 16:24 19:3,8,13 20:7,8,15,17,19 22:25 23:6,9,10 30:12 31:11 33:14 59:16 60:15 70:25 71:15 72:4 75:6 75:10 78:9 80:18 80:19 93:25 97:15 98:2 publishers 75:8 pulled 51:3 58:25
--	--	--	--	---

purchased 14:25	35:24 46:4	47:21	reliability 12:13	63:18 64:3 87:15
purpose 11:3,5,6 59:1	quite 4:20 41:18	recommend 65:15	23:25 26:6 77:21	92:24 95:6
purposes 89:17,18	quote 13:10 25:17 29:17 41:25 64:2	recommendation 55:17	77:21 78:3 89:18	reporter 7:15 101:5
put 25:11 46:25	91:9	recommended 13:4	91:3	reporting 1:23
60:11 72:15 77:6	quoted 61:22	19:16 20:11 36:17	reliable 23:4 48:13	18:11 42:6 43:4,7
93:23,23,24,24	<hr/> R <hr/>	93:9	54:3 56:25 57:11	95:17
96:7,8,9 97:14,19	R 1:13 101:1	record 34:15 37:4	64:21 88:7 89:9	reports 4:4 10:12
98:1	raise 89:16	40:14 42:25 71:4	reliably 12:5	13:20 14:12 16:7
puts 32:24 60:13	raised 78:17 85:19	recorded 1:21	reliance 13:1	16:18 17:11 18:19
80:17	Ralphie 97:10	37:24	relied 65:14 78:4	56:17,21 57:20
putting 81:4	range 66:10	recording 1:21	relies 14:6,8	70:3 72:1,25 74:3
p.m 100:25	ranges 36:18	recordings 101:7	relitigate 53:14,15	76:20 77:5 78:25
<hr/> Q <hr/>	rat 34:16	redesigning 61:11	rely 13:7 61:14	83:21 86:10 89:25
qualification 42:14	rate 39:13,14 44:12	reduction 61:9	77:25 82:11 91:17	90:21 91:17,17
qualified 73:12	44:15 51:19,20	reevaluating 47:24	relying 56:21 98:25	report's 69:16
qualify 70:20	ratios 16:25,25	47:24	remain 87:16	represents 19:24
qualifying 42:23,23	18:11	reevaluation 48:15	remainder 87:11	request 8:2,3 46:13
quality 77:5	read 7:17 40:14	refer 13:11 31:23	remaining 22:4,5	86:5 91:15
quantities 34:14	86:13	53:4	23:17	require 53:14
98:22	readers 41:24	reference 12:11	remains 87:12 89:3	requirements
quarterly 20:3	51:22 64:13	13:25 18:1 33:9	remarkable 69:3	42:14
queried 24:23 38:7	reading 7:18	36:9 38:6,6,7	remember 47:20,20	requires 31:20
38:11,22,25 44:1	real 82:3 85:1	referenced 38:5	69:24 97:9	50:22
query 25:2 39:8,8	reality 93:12	references 14:2	remind 35:5	research 42:6 43:4
question 15:18 17:5	realize 76:16	referred 54:20	reminder 15:12	50:12 69:19
17:15,18,20 18:10	really 33:16 65:11	referring 13:12	24:10	researcher 42:2
18:18 21:3,4 22:5	79:5 82:10 87:18	reflected 8:18	Renaissance 2:6	researchers 15:6
22:9 24:2 26:6	90:22	REGION 1:23	renewal 68:18	43:13
30:24 31:1 32:25	realm 93:5	Registered 101:4	repeated 55:25	researching 43:8
35:4,7 42:21 43:1	realtime 9:5 85:1	registry 16:19 24:9	replicated 56:25	reserve 5:20 52:6
44:2 45:5 48:12	reanalysis 87:16	46:21 60:7 62:23	reply 6:21,21	resign 79:17
49:1 51:3,4 53:12	reanalyzed 49:6	80:9	report 4:11 14:1,2	resistance 49:17
54:19 59:12,14,19	reapproved 67:1,1	regulation 50:6,6	15:23,24 16:4,9	resolution 24:24
60:2 68:21 69:6	reason 33:1 43:24	regulatory 61:16	16:13 18:7,23	respect 4:11 45:9
70:5 74:14,16	45:1 46:11 85:7	62:16 77:24	24:4,6 26:18 27:3	51:11 63:18
81:13 89:15,16	reasonable 21:7	reiterates 56:15	29:4,8 35:17	respectfully 73:2
92:20,22	82:22	related 67:10,15	38:13,16 64:23	86:5
questionnaire 6:11	reasons 88:5 96:2	69:21 80:17 91:1	66:6 69:15 73:17	respond 96:16
questions 12:10,16	rebuffed 15:17	relates 6:3,15	74:21 78:13 80:12	responded 16:3
20:25 25:10,11	recall 13:24 25:6	relating 27:1 30:17	80:24 82:2,5,17	17:22 21:8 28:18
29:12,13 54:2	41:11 58:5 79:16	80:19	82:19,25 83:2,2	responses 25:2
58:19 60:24 61:14	80:23 83:16	relationship 18:25	83:24 85:9 86:22	responsible 10:17
73:21 78:17	received 31:12 74:3	relative 17:1	92:18 93:24 99:6	rest 54:11 60:15
quick 8:7 31:4	recipients 43:5	relevance 36:15	99:14	62:14,14,15
quickly 26:8 35:23	reclassified 47:17	relevant 26:5 30:16	reported 16:7 28:8	result 31:2 66:16
		33:6	28:10,11 54:21,22	results 54:21 95:5
			59:22 60:9 63:2	retained 71:12,19

retracted 70:24	21:6,7 23:7,10,13	seconds 99:16	shift 77:13	57:10 92:12,25
retrospective 80:1	56:20 58:6	section 26:9,19,25	shock 70:9	six 26:22 41:10
returned 25:2	safety 54:8,11	27:2,4,6,8 32:11	shoot 97:11	72:23 78:17
returning 69:12	55:18 61:12 65:17	33:10 35:20 36:10	short 11:9,10 51:17	six-years 62:23
review 37:11 51:24	67:23 68:4,7	38:5 58:13,14	71:24	skepticism 91:4
53:17 68:17 77:19	93:20	63:24 84:11	shortly 4:5 45:11	skipping 64:6
reviewed 24:22	SALES 1:5	sections 26:4 27:15	show 32:8 35:13	slash 7:3
30:13 44:21 66:1	sat 67:8	SEDRAN 1:11	40:7 56:4 64:15	slide 21:23 22:3
reviewers 31:10	savvy 8:7	see 22:7 26:20	75:2,2 89:24	45:19
41:24	saw 28:19 30:5	28:14 30:10 32:10	90:16	sloppy 80:16
reviewing 37:10,13	37:11 38:6 83:12	35:20 37:6 39:16	showed 21:23	small 65:17
re-categorized	95:2,17	40:11 45:18 47:2	27:21 45:19 47:18	smoking 90:15
46:20,21	saying 25:15 80:12	52:9 55:21 57:7	76:8	97:22 99:20
Ridgeland 2:7	81:6,25 90:24,24	60:19 72:18 74:7	showing 48:15	snippets 58:3 59:2
right 5:2,11 6:2 8:5	says 25:18 33:19	75:25 76:2 78:10	shown 44:16	SNOW 2:2,5
8:10,11 9:21 12:1	38:15 48:3,7 50:1	78:12 80:4,10	shows 39:6 41:20	somebody 25:9
14:18 22:9,9,19	55:11,23 56:19	82:5,10 83:8	56:10 75:16 90:17	34:24 36:10 37:23
22:20 33:17,22	74:22 76:13 77:16	88:19,20 100:21	90:18	41:14
34:2,6 35:4,8	78:2 81:18 82:1	seeing 46:14	sic 69:2 77:9	sorry 24:15 40:13
38:23 40:20 45:16	84:21 85:9 88:1	seen 7:21 51:13	side 11:15	sought 76:12 79:3
52:3 55:19 58:24	92:21,22 93:25,25	62:22 68:22 79:12	sidebar 11:23	sound 1:21 101:7
90:19 96:13,18	97:10,16	selection 6:25	signed 34:20 37:8	source 77:4
ringing 24:13	schedule 11:13	senator 50:11,14	86:19,19,23	so-called 12:3
rise 100:23	scheduled 11:13	sending 49:5	significant 8:20	78:24
rises 30:20	scheduling 7:5 9:24	senior 71:9	18:7,12	SPEAKER 8:4
risk 16:24 18:11	Schiodt 19:14	sense 78:12	similar 10:1	24:15 40:18,24
26:15 54:15 56:2	science 18:21 22:21	sent 29:5 34:18	simple 37:21	100:17,20
56:6,18 57:4,22	39:15 44:14 45:8	45:3,4,6 86:9,17	simply 17:11 34:24	specific 15:13 16:5
58:7,10,17,23	50:21 61:15 85:2	86:23	41:22	18:10 25:24 38:6
61:8 65:18 76:10	93:6 94:3	sentences 64:7	single 13:7,9 15:1	specifically 17:13
risks 17:1	scientific 19:3	sentencing 11:13	18:1 36:4 41:21	17:15 18:24 24:3
Road 1:15	23:25 31:13 57:21	sepsis 70:9	49:12,14 53:23	27:1 28:3 29:18
Robuck 42:8,19	61:16,20,25 62:15	September 10:23	62:12 68:19 70:19	39:15 53:21 59:13
43:3 49:25 66:19	63:16 72:12 78:14	13:16 52:19	75:11 89:9,10	59:19 64:4 67:18
67:8 68:20 71:17	79:8 99:2	series 16:6,17,19	96:6 99:20	spectrum 57:18
78:6	scientist 42:22 74:4	17:12 18:19 20:2	single-spaced	62:21 63:9 65:21
Robuck's 43:12	81:12 82:23	79:10	87:12	94:19 95:20
role 12:14	scientists 22:20	serious 35:23	sink 25:18	spend 64:19
RPR 2:9 101:13	42:13 54:18	service 1:22	sinks 14:4	spent 63:14 65:4
rule 7:9 12:14	screen 32:8 35:19	set 4:23 6:4 65:19	sir 7:24	68:10
ruling 7:11	Screens 27:9	66:22,24 100:16	site 29:9,13 30:7	SPIEGEL 1:14
rulings 9:15	scrupulously 68:16	100:18	33:7 36:22 38:9	sponsored 42:9
running 60:6	sealed 31:20	setting 50:22 57:10	41:6,7 71:13 72:6	sponsorship 50:15
	second 4:19 12:21	88:25	76:18 83:3,3,5,6	spreadsheet 27:25
	15:4 18:22 22:8	seven-day 6:21	84:23,23 85:13	28:2,23 37:15
	24:1 33:5 34:20	severe 64:8	sites 24:9,19,23	46:8 47:1,6,7,8,16
	47:25 82:1 87:9	shared 9:10	situation 34:12	66:15
S				
S 1:10 3:12				
safe 19:17,22 20:10				

spreadsheets 45:25 48:15	15:12 16:23 17:10 18:5 21:15 24:9	suggested 47:7 53:16 78:23	taken 9:6 19:16 28:15 36:6 49:15	43:12 45:17 50:7 51:17 58:14 59:9
squarely 61:21 62:4	24:18,18 32:12 33:7 36:21,22	suggests 54:14 57:17 64:8	52:23 61:8	94:18
stand 15:5 19:21,23 20:13 51:16 57:16	40:1 41:10 42:12 42:20 43:24 44:1	suicide 34:16 37:1 37:23,25 63:4	takes 46:2	testing 50:23 76:1
72:11 91:10	44:3,4 46:10	64:1	talk 10:11 14:18 15:24 27:9 34:7	89:13 98:19
standard 81:9,14	50:12,15,17,18,19	Suite 1:11,14,18,24	59:15 63:10,25	Texas 31:7
standing 5:12 62:3	50:22 51:2,3,5	2:6	65:8,8 75:11	text 81:19
stands 61:20	52:2 53:16 54:3	summaries 67:20 68:2	77:13 78:25 79:5	textbook 72:4
start 12:9 57:15 58:2	54:10,12,14 56:4	support 12:6 55:25 65:25	80:21 85:16 91:14	thank 7:24,25 10:6
started 41:10 45:22 60:20	59:21 60:9,22 62:5,8,13,18,25	supervised 68:16	talked 47:11 63:13 80:22 90:12 95:21	10:7 11:12 12:2
startling 57:25	63:2,3,5 66:2,22	supervision 76:24	98:11,17	14:21 32:5,6
state 6:18 29:11 35:23	67:2,11 68:5,8,13	supplement 4:12	talking 63:15 64:19 65:5,23 86:15	52:11,12,15 96:11
statement 19:18 20:16 45:17 50:7	68:14,22 69:1,3,8	supplemental 4:4 10:12 92:18	talks 55:16 74:2 80:21	96:12,20 98:9,9
87:25	69:23,24,25 70:22	support 12:6 55:25 65:25	Taylor 6:3,7 60:25	99:4,5,9 100:8,9
statements 23:19 59:15	70:23 71:8,10,18	supports 50:6	technologically 8:7	100:20
States 1:1,8 14:16 76:23	74:11,18 77:15,22	supposed 81:10 94:1,1	technology 40:15	Thanks 53:11 84:16
stating 23:6	77:25 78:3,7,18	supratherapeutic 56:1	telephone 1:7 41:6 41:7	theory 13:3,6
statistically 18:7,12	78:21 79:18,25	sure 4:20 8:22 9:9 11:21 32:4,19	television 72:9	therapeutic 28:13
status 1:7 26:14 35:22	80:1,2,8,13,20	53:7 84:4	tell 23:12 28:4 99:2 99:3	32:19 57:22 61:7
steering 67:7,9	81:5,24 82:4 84:7	surprise 5:18	telling 79:13	64:9
STENGEL 1:7	87:8,21 88:13	surprised 4:21	tells 44:24 75:17 91:11	thin 6:16
stop 22:1	89:3,17 90:19,20	surprising 64:18	term 16:13	thing 17:23 26:18
Story 97:9	92:21,22 93:2,6	suspect 74:25 75:18	terms 4:6 9:13 11:12	27:13 57:14 66:18
straightforward 53:13	93:10 95:5 97:14	swims 14:4	test 33:17,19 50:23 74:7,12 90:10,14	75:22 86:21 93:11
Street 1:11,18,24	98:3,24	symptoms 64:5	92:11	98:10
strenuous 31:5	studying 70:1	S-c-h-i-o-d-t 19:14	tested 90:7,8	things 9:3 16:5,16
stretched 6:16	study's 40:9	T	testified 13:18,22 17:4 30:4,14,19	52:21 59:15 61:10
strike 85:18,22,24	subanalysis 80:7	T 3:12 101:1,1	33:23 39:22 40:17	62:20 68:25,25
struck 91:16 94:5,7 94:7 96:1	subject 42:14 68:17 68:18 76:1	39:22 55:10 72:14	42:11 43:9,19	69:25 70:4,4,9,9
struggling 93:13	submissions 99:12	79:10 81:16	46:5 51:1,15	70:13,14,14 74:6
student 46:12	submit 23:2,24 32:22 42:5 54:3	tabbed 73:9	58:15 66:13,19	74:15
studied 63:1 76:6	78:2	table 85:4 90:5 97:25	67:17 75:14 87:10	77:15 82:6 86:3
studies 15:11 51:24 74:12 88:12 91:4	submitted 37:8 78:7,8 86:24	tablets 37:20	98:18	79:13 82:6 86:3
study 6:20 7:7 12:4 14:11,15,19,23	97:20	take 11:15 21:8 37:16 40:2 53:9	testify 14:15 20:23	90:3,3 93:14
	subsequently 73:19	60:16,18 66:14	testimony 14:7 17:2 21:2 31:12	95:23 97:13 99:14
	substance 87:2	72:15 81:8	35:13 39:5 41:20	thinking 19:24
	substantial 32:24 34:13			third 12:23 15:9 30:25 89:24
	substituted 89:4			thoroughly 86:7
	sudden 64:7			thought 7:9 24:16
	suggest 56:22			

83:13,19 thousand 40:3 three 31:15,24 33:8 35:2,7 39:11 44:17 49:8 54:5,9 68:19 69:16,18 70:16 89:23 throws 50:19 52:3 thrust 95:10 thumb 7:15 8:3 time 6:14 10:25 11:4,10,10 20:19 24:20 28:12 31:15 49:17 52:7,10 54:16 63:14 64:19 65:5,24 68:11,19 71:24 78:22 91:20 93:15 96:7 times 37:7 61:23 Tisi 1:17 3:4 11:17 11:18 52:13,14 53:8,12 55:8,9,13 55:15,20,23 58:22 58:25 59:5 66:8 74:2 81:16,20,23 84:1,5,17 86:3 88:21 91:7,8 96:12 97:1 98:1 98:17 99:6,8,10 99:13,18 100:1,13 100:22 today 4:13 7:8,13 7:22 11:11 13:11 15:24 29:7 32:23 32:25 38:20,22 39:1 41:9 44:2,10 44:19 49:9,12 51:16 87:13 today's 4:23 7:16 told 19:3 21:11 23:16 42:19 45:14 49:10,11 64:13 98:4 100:7 topic 82:9 total 36:7 47:25 tough 21:9 Tox 27:9	toxicity 56:22 71:11 74:8,9,23 75:16 99:21 100:6 toxicologists 72:7 toxins 26:22 track 16:5 tracked 26:15,16 tragic 34:12 tragically 34:17 TRANSCRIBER 2:9 transcript 1:7,22 7:13,16 8:2 101:6 transcription 1:22 transcripts 9:5 transferred 8:21 transplants 73:4 treat 63:7,8 treaters 6:10 treating 36:21 38:7 tremendous 71:24 trial 6:4 13:15 17:9 52:17,19 53:23 57:3 61:14 88:1 95:8 trials 57:19 tried 37:21 true 43:6 48:1 49:10 54:17 63:21 91:12 93:1 101:6 truth 68:11 94:8 96:23 try 47:11 trying 7:20 9:18 12:10 62:2,10 63:6,7,8 64:1 turn 14:6,8 17:13 24:1 30:25 65:21 73:22 turned 86:17 two 4:9 6:7 18:16 19:10,15 20:7,18 23:9 27:15,15 31:7,18 35:10 37:8 49:2,7 54:8 56:21 60:23 61:6 61:13 69:22 70:11	71:2 72:7 79:8 80:4,11,22 82:2 84:6,6 87:3,14 88:17 96:16,18 98:22 Tylenol 1:4 32:13 34:14 36:5,24 37:18 38:5,8 types 25:9 typical 36:15 typically 53:3 <hr/> U <hr/> ultimately 53:24 77:9 Um-hmm 99:25 unacceptable 39:14 unbeknownst 82:24 unbiased 74:16 unblinded 41:22 uncertain 22:11 uncertainty 22:22 23:22 underlying 12:13 understand 24:5 26:5 33:20 62:2 72:9,11 74:24 understanding 69:4 understands 71:4 undo 62:10 unfolded 65:22 unfortunate 34:12 unilaterally 42:13 43:15 unintentional 64:3 unique 68:13 United 1:1,8 14:16 76:23 unknown 36:1 39:3 64:23 unquote 13:10 unrelated 98:16 unreliable 12:24 56:17 63:15 65:5 81:7 82:21,22	85:12 90:2,10 94:5 95:16 update 7:4 updated 20:4 up-to-date 4:16 use 11:3 36:25 59:6 59:7 64:9 88:1,11 uses 16:13 usually 41:5 UTSMC30059 46:9 UTSW 24:21,22 31:20 U.S 14:25 50:10,14 <hr/> V <hr/> V 1:17 vacuum 66:23 valid 51:8 validated 92:11 93:5 validity 53:16 various 58:15,16 59:3,9 60:21 68:23 75:4 verified 27:24 29:1 verify 30:6 VERITEXT 1:23 vetted 38:10 Vicodin 36:5 video 5:17 11:3 videotapes 11:6 view 12:5 violation 42:3 virtually 13:18 21:24 visual 11:5,7 vital 25:18 vitamins 26:24 votes 62:7 <hr/> W <hr/> wait 82:1 waive 42:13,14,22 waived 40:11 41:2 41:3,3,11,22 43:16 waiver 41:4,23	42:20,21,24 43:18 waivers 43:9 walk 26:8 Walnut 1:11 want 8:22,22 9:8,8 9:9,22 16:11 19:6 59:14 65:11,21 79:5 83:18 85:20 85:25 87:4 88:10 89:23 96:14 98:5 100:16 wanted 4:19 7:3 16:5 28:13 32:8 46:6 95:22 96:16 wants 8:23 9:11 44:14 warn 6:7 Washington 1:18 6:18 29:11,11 wasn't 37:10 61:25 85:19 watch 72:9 way 13:12 25:16 26:2 51:8 74:19 75:19 85:10 92:17 95:24,24 week 6:17 well-accepted 18:21 went 22:15 24:5 29:12 48:21 49:8 67:22 86:18 95:24 weren't 70:1 90:25 we'll 4:5 11:15,15 27:9 34:7 78:25 we're 5:14 6:9,12 7:23 8:24 11:6 15:24 20:14 24:4 31:23 34:9 52:22 60:20 65:23 94:1 94:1 96:13 98:4 we've 21:15 31:17 35:7 49:6 95:21 96:4,5 widely 72:2 William 71:6 willing 71:22,23
---	---	---	---	--

window 89:13 90:4	50:14 52:1 60:14	10:19 11:24	62:25 63:12 64:20	44:12,15 49:20
wish 83:14	64:23 82:2,7,25	10:21 11:24	65:9 66:4 77:1	51:20 82:14 91:9
withdraw 35:13	98:1	10019 2:3	82:18 89:5 90:7	215 1:12
withdrawn 19:25		107 92:14	94:20,22	23rd 6:25
20:16 31:15 33:3	X	108 92:14	19103 1:24	2450 1:14
33:15 35:7	X 3:1,12	11 53:22 55:3,15	19106 1:12	256 27:19
withdrew 32:14	X'd 31:18	60:3 66:10 83:1	1997 25:25	27 1:5
33:5 35:6,10		116 46:20 47:18	1998 19:9,11 22:24	275 27:19 63:1
witness 42:9 99:21	Y	48:9,9	41:11 62:24	28 14:24,25
witnesses 49:16	Y 2:9 101:4,13	12 3:4 25:25 82:15	2	286 92:21
58:1,15 59:9	Yeah 40:22 41:1	82:19 84:1 88:16	2 30:10 45:16,18,19	29 80:10 81:17
73:13,15	year 6:9 13:17	99:24	46:7 48:6	101:13
word 87:6	60:20 96:5	12.5 88:23	2:00 11:14	29th 9:25 82:17
words 23:20 28:22	years 19:10,20 20:7	12:23 100:25	2:13-md-02436-LS	299 40:7
81:23	20:18 23:9 31:7	12:30 11:14	1:4	3
work 7:14 37:22	36:1 38:22 59:16	120 36:14,19	20 36:18 68:5,24	3 30:12 46:8 58:23
59:20	60:16 68:5,14,19	13 19:20 26:9 35:20	71:7	79:10 97:23 98:21
working 6:5 14:1	68:24 71:8 93:14	1368 27:21	20-year 59:20	30 29:1 36:18 71:15
54:19,25 55:4,11	yesterday 4:14 7:2	1370 63:24	20006 1:18	99:16
56:15,19 62:4	85:25	14 35:18 38:22	2002 38:11	30th 82:8,9
65:14	York 2:3	73:23,25 87:6	2003 19:9,12,13,25	30326 1:15
world 15:6 60:7		1400 2:6	22:24 23:6 58:8,9	322 98:20
worries 8:9	Z	15 59:16 60:16	60:13 62:24	325 37:18
worse 97:8	Zimmerman 21:19	73:23,25 90:6	2005 12:5,19,22	34 72:22 83:1
worth 27:2	21:19	93:14	13:19 14:2,23	35-year-old 34:13
wouldn't 42:25	0	150 71:10	15:4,9,15 17:14	36:23
woven 78:25	008 39:21	152 72:21	17:19 18:24 19:8	36 72:22
wrangling 96:7	010 64:25 82:15	16 39:13 49:20	20:8,19 23:4 24:3	37 83:1
wrap 45:10 53:22	88:9,16,17 99:24	51:19 87:15 89:4	27:17 33:25 34:5	39158 2:7
91:7 95:21,22	026 31:25 32:2	89:19 90:7	38:12 45:22 46:14	4
write 19:10 20:13	035 33:5	16th 6:12,23	47:25 49:4 50:25	4 3:2 12:6 13:14
22:9 29:8 31:2	042 35:12,17 46:16	17 53:22 59:12	65:12	14:5 17:6,21 18:9
66:17 73:8,10	47:2 48:3	87:15,15 89:4,19	2006 50:11 52:1	19:5,16 20:11
74:21	051 46:17	1700 2:3	2007 20:5 23:10	23:6,10 28:9,21
writings 23:19		18 26:25 87:16 90:7	45:14,18,23 47:14	32:20,21 40:3
written 20:18 24:20	1	90:7	48:1,4,8,20 49:2	48:14 56:5,23
27:24 28:2 30:10	1 20:11 24:7 72:14	1800 1:24	99:2	57:3,23 58:10
32:12 33:8 34:15	85:4 90:5	1801 1:24	2009 20:22 23:12	59:24 61:4 76:25
37:7 44:24 89:17	1,200 36:10,11	1825 1:18	45:14,18,23 47:14	83:11 89:1,6,20
99:11	37:14,16,20,22	19 12:3 13:23 14:3	48:1,4,8,20 49:2	98:19
wrong 22:19 24:5	38:1	14:8 15:16 20:20	2011 97:14	4-gram 76:7 100:2
62:16 74:5 90:21	1.0 97:17	22:23 23:3 26:7	2013 21:13 23:16	404 1:16
95:6	1.2 36:11	27:22 28:3,5,7	2015 80:3,5	41 30:9 87:9 97:24
wrote 19:15,20	10 30:9 32:19 55:16	29:17,18 30:11,20	2016 1:5 29:1 65:23	42 30:9,12
20:5,9 22:7 25:15	56:1 58:8,18,23	31:15 32:2 33:14	80:5,10 81:17	48-page 87:11
29:4 35:10 36:10	59:16 60:5 83:1	35:15 39:11 45:4	101:13	
36:23 38:12 50:10	10:11 1:6	51:11 54:10 57:8	202 1:19	
			21 21:23 30:13	

5

5 56:11 59:25**50** 32:18**500** 1:11**500-milligram**

37:19

510 1:11**52** 3:4**592-1500** 1:12

6

6 32:16 59:25 76:6**6-gram** 32:24**601** 2:7**606-2995** 2:4**646** 2:4

7

7 83:9 98:21**7.5** 56:11 64:10

87:8

700 1:18**702** 12:15**777-6690** 1:25**783-6400** 1:19

8

8 15:1**80** 35:25 36:1**832-8000** 1:16**86** 58:19 59:11**88** 72:21**888** 1:25

9

9 39:22 88:7,16

100:3,3,5

9th 6:12,21**950** 1:15**96** 3:4**985-4427** 2:7**99** 3:4