

P R O C E E D I N G S

IN OPEN COURT

1
2
3
4 THE COURT: Okay. We got the Viagra products
5 litigation and, Ms. Leskin, do you want to tell me about
6 this.

7 MS. LESKIN: Yes, sir. I'll get started, your
8 Honor. Your Honor, before we begin, can Mr. Hopper and I
9 approach?

10 THE COURT: You can talk out loud. We haven't got
11 a jury to hide from.

12 MR. HOPPER: We wanted the Court to understand the
13 procedure that we're going to follow.

14 THE COURT: An hour a piece and you're going to
15 get 15 minutes for rebuttal.

16 MR. HOPPER: Mr. Becnel would like to speak first
17 on our side.

18 THE COURT: Take away from your side. That's the
19 way it goes. I don't care who talks. I think by and large
20 you're all admitted and licensed and all of that.

21 MR. BECNEL: May it please the Court, I'm going to
22 leave my phone not on but on vibrate. My 92-year-old mother
23 is having surgery right now and it doesn't look good. My
24 sister is going to call me. She's a nurse so I told her to
25 call me. Is that okay?

1 THE COURT: We want to certainly pray that things
2 will go well.

3 MR. BECNEL: I hope so.

4 THE COURT: By all means leave it on and we'll get
5 you away as soon as we can.

6 As a matter of fact, Mr. Becnel --

7 MR. BECNEL: That's why I may jump out on you if
8 things don't go right.

9 THE COURT: -- should circumstances arise that you
10 need to leave, leave.

11 MR. BECNEL: This just happened last night so I
12 was already here.

13 THE COURT: I understand. Okay.

14 MS. LESKIN: May it please the Court, as your
15 Honor knows my name is Lori Leskin and I'm here today on
16 behalf of Pfizer's Motion to Exclude Plaintiffs' Experts.
17 Daubert requires that an expert's testimony be both relevant
18 and reliable. This means at the outset this Court must make
19 the determination that the reasoning and methodology
20 underlying the testimony is scientifically valid.

21 Daubert, as we all know, has four nonexclusive
22 factors to guide the Court's consideration here. The Eighth
23 Circuit has recognized that known or potential rate of error
24 is not relevant here where we're not dealing with the
25 specific technique but rather causation theories.

1 Plaintiffs spend much of their briefing talking
2 about the qualification of their experts. But as the Court
3 well knows, expertise is not sufficient. As your Honor
4 wrote in Solheim Farms, both Daubert and Kumho make it clear
5 that the day of the expert who merely opines and does so on
6 the vague notions of experience is over. Experts are held
7 to a degree of accountability that requires factual
8 predicate, an historical fact of competent evidence which
9 allows the fact finder to independently verify the accuracy
10 of the results. And in the absence of such reliable
11 verification, the expert's opinion is not admissible.

12 This conclusion follows the case law elsewhere.
13 In Rosen, for example, the Seventh Circuit -- the Seventh
14 Circuit affirmed the exclusion despite the sterling
15 credentials of the expert because the expert's opinion
16 lacked scientific rigor and lacked any experimental,
17 statistical or other scientific data from which a causal
18 relation might be inferred. And as Rosen warned, the
19 courtroom is not the place for scientific guesswork, even of
20 the inspired sort. Law led science. It does not lead it.

21 So let's go through the Daubert factors and the
22 first factor is testing, whether the theory can be and has
23 been tested. NAION, Nonarteritic Ischemic Optic Neuropathy,
24 is a recognized medical condition, has been around for more
25 than 50 years. And it's undisputed that NAION occurred in

1 men long before Viagra was ever introduced to the market.
2 And it's also undisputed that NAION continues to occur in
3 men today, even those who do not take Viagra. But men who
4 take Viagra are not immune to NAION and so, of course, some
5 of those men will, too, get the disease.

6 It's undisputed and every expert has acknowledged
7 that the risk factors for NAION and erectile dysfunction
8 overlap and because of this overlap it's not surprising that
9 some men who take Viagra will get NAION, not because of the
10 drug but because of their underlying medical condition.

11 So the essential scientific question that must be
12 tested is whether men who take Viagra experience NAION more
13 frequently than men who have not taken the drug.

14 So you have to look at the evidence of testing
15 that exists. In their brief Plaintiffs identify the
16 universe of evidence supposedly supporting their expert.
17 They look at animal studies, human clinical studies,
18 epidemiology studies, case reports, challenge-rechallenge
19 cases, and a proposed mechanism of action. But the evidence
20 that we'll go through that they cite do not a provide a
21 reliable factual basis for any of the experts' opinions.

22 Focusing first on the animal studies and the human
23 clinical studies, it's undisputed that while Pfizer
24 developed the drug, Viagra was tested in more than 13,400
25 men and not one of those men had an incidence of NAION.

1 None of the experts cite a single human clinical study that
2 shows anything to the contrary. The only animal studies
3 that were also done were also the animal studies done by
4 Pfizer, and those studies did not find any evidence of a
5 long-term injury to any tissue in the eye and any ocular
6 blood vessels. And, again, none of Plaintiffs' experts were
7 able to identify any studies demonstrating that Viagra
8 caused long-term injury. To the contrary, not one of them
9 conducted any animal studies themselves.

10 And to summarize by Dr. McGwin:

11 "Q. And you acknowledge in your expert report
12 that there's no direct experimental evidence regarding the
13 association between Viagra and NAIION in the form of human
14 clinical trials or laboratory experiments involving animals,
15 correct?

16 A. Yes, sir."

17 Dr. McGwin, in his expert report, cited an article
18 which did discuss Pfizer's animal studies.

19 "A. Yes, sir.

20 Q. Okay. And it indicated for a couple species
21 of animals, dogs and rats, were administered very large
22 doses of Viagra, doses that were 60 to 150 times the human
23 therapeutic equivalent dose, correct?

24 A. Yes, sir.

25 Q. And they were dosed at this very large range,

1 this 60 to 150 times the equivalent human dose, for periods
2 of time ranging from 6 to 24 months, correct?

3 A. Yes, sir."

4 To be clear, this is Dr. McGwin and he is being
5 questioned by my colleague, Mr. Slonim. But talking about
6 the results of these studies, this is how Dr. McGwin
7 acknowledged.

8 "Q. Okay. And in other words, what they are
9 saying is that there was no evidence of injury to the optic
10 nerve, the retina or any portion of the eye or visual
11 system; isn't that correct?

12 A. Yes, sir."

13 And Dr. Aruna similarly acknowledged.

14 "Q. In your expert report you have not cited a
15 single scientific study involving animals in which it's been
16 concluded that the pharmacological effect of Viagra on the
17 animal can cause NAION, correct?

18 A. I have not cited any such -- any animal study
19 that shows that."

20 Dr. Hayreh and Dr. Pomeranz also admitted that
21 they didn't even review the animal studies that have been
22 done by Pfizer. So we've taken care of the animal studies
23 and human clinical studies. So let's talk about
24 epidemiology.

25 As detailed in the briefing on this motion, there

1 are three different studies that have looked at the
2 epidemiology and looked at the association between Viagra
3 and NAION. The first one was done by Dr. McGwin. The
4 second was by Margo & French using the VA database. And the
5 third by Pfizer employees with a lead author of Gorkin.
6 Every expert agrees that these studies do not establish a
7 statistically significant association between Viagra and
8 NAION. As Dr. McGwin testified:

9 "Q. Dr. McGwin, none of the studies that we've
10 reviewed today - your study, the Margo & French Study, or
11 the Gorkin paper - find a statistically significant
12 increased risk of NAION among men who use Viagra, correct?

13 A. That is correct."

14 And he confirmed.

15 "Q. And you're not aware of any studies that we
16 haven't discussed that reports that men who have used Viagra
17 are at a statistically significant increased risk of
18 developing NAION, correct?

19 A. I am aware of no such studies.

20 Q. In other words, we've covered the universe
21 today?

22 A. Unless something came out while we were
23 sitting here."

24 Dr. Hayreh agreed.

25 "Q. Are you aware of any clinical studies showing

1 an increased rate of ischemic optic neuropathy in patients
2 taking Viagra as compared to similar patients not taking
3 Viagra?

4 A. Nobody done that study.

5 Q. Okay. So you don't know of any studies?

6 A. I am not aware of any."

7 Dr. Pomeranz.

8 "Q. So the epi studies that have been done do not
9 demonstrate an increased rate of NAION in patients taking
10 Viagra?

11 A. I think it shows some minimal increase. I
12 think using the epidemiological numbers that they come up
13 with, which I don't pretend to be intimately familiar with,
14 I'm not an epidemiologist, they suggest a trend toward
15 increase. But I don't think anything has been proven or
16 disproven."

17 And the last expert, Dr. Aruna.

18 "Q. You agree with me that you have not cited any
19 scientific studies, any study where there is a control --
20 where there is a control group or comparative group where
21 the study concludes that Viagra can cause a NAION, correct?

22 A. Correct."

23 So the efforts to use the epidemiology as
24 affirmative support is not supported by the testimony of
25 Plaintiffs' own experts. Plaintiffs point to Dr. McGwin's

1 study claiming that this odds ratio of 1.75 is significant
2 to the question of causation even though the finding is not
3 statistically significant. We talk about statistical
4 significance in terms of a p-value and the p-value simply is
5 the probability that the finding that's being reported is
6 due to chance. And in the field of epidemiology it's
7 recognized that the p-value has to be less than .05 as a
8 definition of statistically significant. And the reason, as
9 Dr. McGwin testified, his p-value is .64. And this is what
10 that means.

11 "Q. And the p-value of .64 means that there's a
12 64 percent probability that the odds ratio that you observed
13 is the result of chance, correct?

14 A. That would be one interpretation of it, yes,
15 sir.

16 Q. Another way of phrasing this, a p-value of .64
17 means that there's a 64 percent probability that the odds
18 ratio was the result of random noise in the data, correct?

19 A. Random noise could be one potential
20 explanation, yes, sir."

21 It is to protect against this very type of
22 scenario that science and the law look to statistical
23 significance and a statistically significant study is the
24 hallmark of a reliable study. The case law universally
25 requires statistical significance in order for a

1 epidemiological study to form the basis of an expert's
2 opinion. The Supreme Court in Joiner affirmed the exclusion
3 of epidemiological studies because the increase was not
4 statistically significant. The Eighth Circuit in Glastetter
5 also affirmed the exclusion of an expert opinion because the
6 paucity of examples presented statistically insignificant
7 results.

8 THE COURT: You know, counsel, as you talk about
9 this statistical significance, which certainly in many, many
10 cases is a hallmark of a case, but it seems to me that the
11 Plaintiffs here are saying yeah, we'll give you the
12 statistical significance stuff because epidemiologically we
13 need to. But what we're really talking about here is a
14 whole breadth of a whole bunch of things that are coming to
15 a conclusion that it is possible as opposed to just picking
16 up the individual pieces.

17 MS. LESKIN: Right. And the law does not require
18 an epidemiological study. But if you're using an
19 epidemiological study, it has to be statistically
20 significant. So either Plaintiffs are relying on the
21 epidemiology, in which they do need a statistical
22 significance, or they are not and then we need to look at
23 what that other evidence is but we did not use the
24 epidemiology as a basis. In Glastetter the Court looked
25 at --

1 THE COURT: So they are hurting themselves by
2 this. But so? Again, we come back to the same thing. It
3 seems to me what they are trying to present here,
4 particularly with the plan, is that, Hey, we got a little
5 bit of statistical significance. We got a little bit, and
6 all these things add up. And when they add up, this is the
7 conclusion that McGwin comes to.

8 MS. LESKIN: The Eighth Circuit in Glastetter
9 looked at each individual piece and said individually they
10 do not add up.

11 THE COURT: That's right. But the Eighth Circuit
12 came back and said in another case -- I can't remember the
13 name of it -- but the Eighth Circuit came back in another
14 case and said, Well, just a minute. In Glastetter we
15 individualized this but maybe we don't.

16 MS. LESKIN: Are you talking about Bonner, your
17 Honor?

18 THE COURT: Um-hum.

19 MS. LESKIN: Bonner is distinguishable if you give
20 me a few minutes to get there.

21 THE COURT: Take your time. We'll note it when we
22 get there. That's fine.

23 MS. LESKIN: We can absolutely get there. I'm
24 just not as good at these as I would hope to be. Okay.

25 THE COURT: How you guys do any of this stuff I

1 don't have the slightest idea. I can't even figure out how
2 to turn the thing on and off.

3 MS. LESKIN: There was a big arrow on there before
4 and we had no idea how to get that off.

5 MR. OVERHOLTZ: Feel free to just turn it right
6 off, your Honor.

7 MS. LESKIN: The main reason Plaintiffs point to
8 Bonner is for case reports. And the Court in Bonner
9 actually did not recognize that case reports by themselves
10 can justify a reliable opinion. To the contrary, the Court
11 noted that the case reports were a shortcoming in the
12 expert's opinion. But Bonner, again, is distinguishable.

13 First, Bonner involved a known toxic industrial
14 solvent. Here, Viagra is an FDA-approved medication that's
15 been used by over 27 million men around the world. In
16 Bonner, it's the immediacy of the reaction of the Plaintiff
17 that supported one -- was one of the building blocks of that
18 opinion. Here, Dr. Hayreh, who has a theory of mechanism,
19 testified that in 11 of the 14 published case reports there
20 was no factual basis for the purported temporal association.

21 Next, Bonner was -- and Bonner, the consumer
22 information specifically warned of the very type of effect
23 that the Plaintiff was suffering and said that this is a
24 known side effect. In Viagra, while the label says these
25 have been reported, the FDA specifically said we cannot

1 determine if Viagra causes NAION.

2 In Bonner there were animal studies that showed
3 that this substance can cause these types of effects. In
4 Viagra, the animal studies, in fact, show no evidence of
5 long-term injury.

6 In Bonner there was testimony that the analogous
7 substances similarly caused the effect and that this
8 substance behaved like those substances. Here, while there
9 may be testimony that Viagra is like the blood pressure
10 lowering medications, there's no evidence that the blood
11 pressure lowering medications caused NAION. And so there's
12 no other substances that we can analogize to.

13 And, finally, in Bonner the expert had specific
14 testing of the very mechanism that they said caused this
15 injury. And as I'll talk to in a moment, here Dr. Hayreh
16 acknowledges that there are no studies. In fact, in
17 Dr. Hayreh's opinion you cannot test his theory of
18 mechanism. So Bonner had several different things that the
19 Court looked to and was able to put together. Here, we
20 don't have a single one of those to talk about. So if we're
21 putting aside the epidemiology, there's still nothing there.

22 So I want to talk about Plaintiffs point to these
23 challenge-rechallenge cases as one of these case reports.
24 And challenge-rechallenge is really no different from a case
25 report. And the Courts have universally recognized that

1 case reports by themselves are not sufficient. And when it
2 becomes a challenge-rechallenge, it also is not sufficient.

3 THE COURT: Counsel.

4 MS. LESKIN: Yes.

5 THE COURT: I think it's fairly well-recognized,
6 apparently, I think it is. It's got to be because the
7 actual test on the NAION apparently can't just be done
8 because of the injuries to the eye and we don't want to run
9 around making a bunch of people blind on purpose. So if you
10 got one of those situations -- and there's got to be lots of
11 them in this world because of the complexity particularly of
12 the human body but unfortunately of many things -- that you
13 can't test. Well, if you can't test by this abstract
14 scientific testing method, what possible thing do you have
15 except case reports? You know, you kind of -- you're just
16 kind of left with it.

17 MS. LESKIN: Well, you have more than just case
18 reports, your Honor. You actually -- first of all, there is
19 testing that goes to the issue here. So the assumption that
20 you can't test for NAION is simply not consistent with what
21 the evidence is.

22 THE COURT: Well, your testing is limited to
23 animals and various kinds of statistical information that
24 comes from that. That's about what you've got. You're not
25 running around deliberately overdosing and all that kind of

1 stuff that goes on.

2 MS. LESKIN: Sure. I mean, everyone acknowledges
3 that case reports can generate a signal; that if you have
4 something that occurs rarely, you look to the case reports
5 to see if there is something unexpected happening. But when
6 you get that signal, and the documents the Plaintiffs have
7 cited to recognize this, all that means is that you
8 investigate it further. You investigate it further by doing
9 epidemiological studies, and three studies have failed to
10 show an increased rate of NAION. And you look at it to see
11 if you can test the mechanism, and that's been looked at.

12 Now, the theory that they are talking that
13 Dr. Hayreh proposes is that we start with his assumption
14 that what NAION is due to. And Hayreh says putting aside
15 Viagra, NAION is caused by this thing called nocturnal
16 hypotension. Well, even that is not well-established. As
17 Dr. McGwin testified:

18 "Q. In the paragraph that you read out loud,
19 there's a portion in which you say NAION is possibly
20 associated with nocturnal systemic hypotension. You used
21 the phrase 'possibly associated' because it's not been
22 scientifically proven that nocturnal systemic hypotension
23 causes NAION, correct?

24 A. That is correct.

25 Q. And, Dr. McGwin, although there are theories

1 about the cause of NAION, which you state in this paragraph,
2 those theories have not been scientifically proven, correct?

3 A. That is correct."

4 We need to back up, though, to understand --

5 THE COURT: A hundred years ago I used to take
6 depositions. One of the things I would always tell
7 witnesses is stop and think about your answer before you
8 give it.

9 MS. LESKIN: Dr. McGwin definitely did that.

10 THE COURT: Fortunately I did that before those
11 days.

12 MS. LESKIN: In order to understand what
13 Dr. McGwin and Dr. Hayreh is talking about, let me back up
14 and talk about what NAION is and what it isn't. This is a
15 schematic of the eye and the optic nerve is this area back
16 here. And what that does is it takes all the vessels and
17 all the nerves from the eye and it comes together in the
18 back through the optic nerve sheath and leads back through
19 the brain.

20 So let me just take out this other one. This is a
21 rough schematic of the blood vessels. The blood to the eye
22 comes off the heart through the carotid artery; and off the
23 carotid artery breaks out into the main blood supply into
24 the eye, which is the ophthalmic artery. From this
25 ophthalmic artery we branch off the central retinal artery

1 which comes up through the middle, feeds the retina and the
2 very superficial layer of the optic nerve; and further along
3 breaks off into the posterior ciliary arteries, the long one
4 of which comes back and feeds the choroid, which is this
5 thin layer of vascular tissue right under the retina. It
6 feeds the retina. And the short posterior ciliary artery,
7 which in turns feeds the optic nerve.

8 If you look at the optic nerve head, this is the
9 very front portion of the optic nerve head. So this area
10 here is the back of the eyeball. And this is the area, this
11 lamina cribrosa, where it is believed that NAION occurs.
12 And the vessels that lead into the optic nerve head are the
13 short posterior ciliary artery that come off the ophthalmic
14 artery and into the optic nerve head.

15 Dr. Hayreh's theory is that at night, all of us,
16 every individual, drops their blood pressure at night. In
17 certain men, or certain people, who have cardiac --
18 cardiovascular risk factors, when that blood pressure drops,
19 it lowers blood flow into the optic nerve and causes an
20 ischemia, a lack of blood in oxygen. So that's his theory,
21 and as Dr. McGwin recognizes, that itself has not even been
22 firmly established. But we don't ask the Court on this
23 motion to decide whether the theory of whether NAION is
24 caused by nocturnal hypotension meets Daubert.

25 But what -- I'll go back to my slides now. For

1 Viagra, what Dr. Hayreh has theorized based on his
2 assumption that nocturnal hypotension causes NAION, he then
3 says that Viagra somehow aggravates this nocturnal
4 hypotension and that in turn that drop in nighttime blood
5 pressure due to Viagra causes a decrease in blood flow into
6 the optic nerve head and that in turn is what causes NAION.

7 Now, Plaintiffs have put forth, and Dr. Hayreh has
8 pointed to no evidence, that Viagra aggravates nocturnal
9 hypotension. No evidence. So what we were talking about
10 before is whether there's evidence that Viagra causes a
11 decrease in blood flow to this area.

12 Now, Dr. Hayreh acknowledged that he didn't do any
13 studies on this.

14 "Q. I just want to know, did you do any studies
15 measuring ocular blood flow following Viagra?

16 A. No, because there's no method to measure the
17 ocular blood flow, period.

18 Q. So you haven't done any studies?

19 A. No."

20 And he did acknowledge that he is not aware of
21 anyone else who has in that area.

22 "Q. Are you aware of any study measuring blood
23 flow to the eyes after Viagra use which shows a decrease of
24 blood flow?

25 A. The ones which you have shown, none of them

1 show.

2 Q. Are you aware of any study which does show --

3 A. No.

4 Q -- a decrease in blood flow?

5 A. No."

6 In the Accutane case --

7 THE COURT: Counsel, isn't the reason for that,
8 admittedly it's a theory, but the reason for that is that
9 you can't study it.

10 MS. LESKIN: Well, but you can study. He
11 referenced that I showed him studies. There were ten blood
12 flow studies that have been done following the use of
13 Viagra. And what those have done is they have looked at
14 other areas of the vessels.

15 THE COURT: But isn't that the problem?

16 MS. LESKIN: But if the closest you can get is
17 every other vessel that leads up into here, then you've
18 tested as much as you can test. So --

19 THE COURT: But it still gets back to isn't that
20 the problem?

21 MS. LESKIN: In the Accutane case the Middle
22 District of Florida recognized that a theory -- a biological
23 mechanism without evidence of the mechanism by which it
24 works is simply a theory, a hypothesis. And what we've said
25 is that the ten studies that are out there which have

1 studied the central retinal artery, have studied the long
2 posterior ciliary artery into the choroid, which have
3 studied the short posterior ciliary artery that leads into
4 the last stop before we get into the optic nerve, and all of
5 those have found either an increase in blood flow or no
6 change in blood flow. None of these studies have found a
7 decrease of blood flow to any vessel in any part of the eye
8 due to Viagra use.

9 And that's consistent with every other study that
10 has been done which universally shows an increase of blood
11 flow throughout the body. This is how Viagra works. It
12 increases blood flow into the penis. It increases blood
13 flow into the lungs in patients with pulmonary hypertension.
14 It's sold as Revatio under the same chemical. And in every
15 vessel that has been tested, every tissue that has been
16 tested, Viagra has been shown to increase blood flow.
17 Nowhere has it been shown to decrease blood flow.

18 And what Dr. Hayreh's theory would have this Court
19 believe is that it's reasonable methodology to look at this
20 one area and say that somehow the blood behaves differently
21 right here than in every other vessel and tissue in the body
22 that has been studied without any studies and any testing to
23 support it.

24 So when you don't have the mechanism and you don't
25 have the epidemiology, and more than you don't have it, what

1 you do have does not show, fails to show an increase in -- a
2 decrease in blood flow, fails to show an increased rate of
3 NAION, then it becomes unreliable methodology to determine
4 that Viagra causes NAION.

5 So after looking at those studies, we don't have
6 not any evidence, no studies to support the part of the
7 theory that Viagra causes a decrease in blood flow to the
8 optic nerve; and as we spoke about, we have no evidence that
9 Viagra causes an increase in NAION in men who take the drug.

10 In the Amorgianos case the Second Circuit held
11 that to warrant admissibility it is critical that an
12 expert's analysis be reliable at every step. Any step that
13 renders an analysis unreliable renders the expert's
14 testimony inadmissible. And that's consistent not just with
15 the law of the Second Circuit. In the Third Circuit the
16 Paoli case held that. In the Ninth Circuit the Domingo case
17 held that; and in the Eleventh Circuit the McClain case also
18 required an expert to show the reliability of each step.
19 And the failure to do that is fatal under Daubert.

20 And all of the evidence that has been presented
21 goes to number one. Plaintiffs' briefs present you many
22 articles that talk about whether or not nocturnal
23 hypotension causes NAION. But none of that evidence goes to
24 numbers two, three and four in Dr. Hayreh's chain, and that
25 is fatal under Daubert. And I'm not the only one who says

1 that. Dr. Pomeranz testified at deposition:

2 "Q. Now, I think you mentioned this. The
3 proposed mechanisms that are out there as to how Viagra can
4 possibly cause NAION, those are all hypothetical at best,
5 right?

6 A. Yes, I think they are hypotheses. I don't
7 think they've been proven or disproven, at least in my
8 opinion."

9 Daubert says if it can't be tested it's not
10 admissible.

11 The next factor is peer review and publication.

12 THE COURT: Counsel, that flat statement that you
13 just made, I don't accept it. I'm sorry.

14 MS. LESKIN: That's the law of Daubert, your
15 Honor. Daubert says the key, the theory can be and has been
16 tested. And case after case says if you are -- you have to
17 be able to test this theory. Otherwise it's hypothetical at
18 best. And every tested -- and this isn't even a situation,
19 your Honor, where there is no testing. There is repeated
20 testing and the testing that has been done again and again
21 fails to find a connection.

22 We talked about -- and that's why you have peer
23 review. And the only published literature that purports to
24 conclude that there is a causal connection between Viagra
25 and NAION is Dr. Hayreh's published viewpoint editorial.

1 But the fact that that viewpoint editorial is published
2 doesn't automatically transform into pure peer review.
3 Because the essence of peer review is publication and
4 replication. And, again, what has been published and
5 replicated are the three epidemiological studies that have
6 failed to find an increased rate of NAION, and the ten blood
7 flow studies that have failed to find a decreased flow of
8 blood.

9 As I mentioned earlier, the FDA concluded that
10 it's not possible to determine whether the events, whether
11 the reports of NAION are caused by Viagra. And when they
12 approved the label for Viagra to make that change, they have
13 reported, again, they issued a statement. And that
14 statement says it is not possible to determine whether these
15 oral medicines cause NAION. And they issue patient
16 information which recognized we do not know if Viagra causes
17 NAION. And when they issued that statement in July of 2005,
18 they said that they were going to continue to review the
19 information and would update it if additional information
20 became available. And that information has not changed.

21 More than the FDA, one of the very studies that is
22 being discussed here, the Margo & French Study, last year
23 looked at the literature and they concluded to date there is
24 no definitive evidence to support a causal relationship.

25 And even Dr. Pomeranz, Plaintiffs' own expert in

1 this case, has repeatedly published that there's not
2 sufficient evidence to establish a causal connection. In
3 2002 he wrote a definite causal relationship between
4 sildenafil, which is Viagra, and NAION cannot be established
5 here. In 2005 he wrote a definite causal relationship
6 cannot be established. In 2006 he recognized that a
7 well-researched explanation as to how sildenafil can cause
8 NAION does not exist, and recognized that the case reports
9 can be an expected coincidence -- those 14 published case
10 reports that we talked about -- because it's the top selling
11 medication and, as I mentioned at the beginning, there are
12 overlapping risk factors.

13 In a presentation he made, Dr. Pomeranz made to
14 his own peers in the scientific community, other
15 ophthalmologists, discussing optic neuropathy, he told them
16 that the relationship between erectile dysfunction drugs,
17 like Viagra, and NAION is unclear and controversial. That's
18 his own words. And so when we got to his deposition this is
19 what he testified:

20 "Q. Is it your hypothesis that Viagra can cause
21 NAION?

22 A. No. At this time, I described in my papers,
23 that there's a temporal association between the two. And
24 I've put forth possible hypotheses, but I don't purport to
25 have a mechanistic answer to that.

1 (Witness pauses.)

2 THE COURT: Counsel, this is the first time in
3 discussion today --

4 "I think it's -- because no one understands
5 completely what the mechanism of NAION is, to cite something
6 as being a specific cause without necessarily knowing all
7 the pathophysiology that underlies a condition I think is
8 difficult to do."

9 MS. LESKIN: I'm sorry. Your question, your
10 Honor?

11 THE COURT: This just happened to be the first
12 time that we've heard this word "temporal" but I got lots of
13 it in here. Help me with the definition of that and the
14 implications of that definition as it applies to this case.

15 MS. LESKIN: "Temporal" solely refers to a time
16 relationship. And in the case of causation, basic causation
17 principles require that a drug be used before the onset of a
18 condition. That is all that is meant by temporal
19 relationship.

20 Dr. Hayreh, as part of his biological mechanism
21 theory, assumed that these 14 published case reports, as he
22 testified, they -- most of them they woke up the next
23 morning with NAION. As that in his mind is consistent with
24 his theory that you take Viagra. It interferes with your
25 nocturnal hypotension, your drop in blood pressure while you

1 sleep, and you wake up the next morning with NAION.

2 But when I confronted him with written case
3 reports, he acknowledged that the reports do not provide a
4 factual predicate for that opinion. And, in fact, in 11 of
5 the 14 case reports the written facts were contrary to his
6 assumptions. And that that was -- and he acknowledged that
7 it was solely his assumption, but not based on factual
8 record.

9 THE COURT: In other words, they had to have been
10 asleep or something that was involved?

11 MS. LESKIN: That's correct. Some of them were an
12 hour but hadn't been sleeping; some of them were 36 hours.
13 Lots of them had no information as to the time between the
14 onset and the taking of the drug. In the Margo & French
15 Study there is no evidence of a temporal relationship
16 between the patients who were taking NAION [sic] and
17 taking -- and taking a drug, one of the drugs. In fact, one
18 of the acknowledged methodological flaws of that study was
19 that there was no effort to insure that the cases had in
20 fact taken Viagra or another erectile dysfunction drug
21 before the onset of their condition, and we have no way to
22 know whether any of those patients had NAION before they
23 took the drug.

24 And obviously if you have the condition before you
25 ever take a drug, the drug cannot have caused that

1 condition. And that, of course, is one of the problems with
2 case reports is the information on temporality is often
3 missing. One of the published case reports in this case, at
4 least one of them, suffers from that very flaw.

5 And, again, all the case reports give you is a
6 potential temporal relationship. The Eighth Circuit in
7 Glastetter recognized the case reports, while they may show
8 a temporal association, make little attempt to screen out
9 alternative causes, lack analysis and omit relevant facts
10 about the patient including medical history, family history,
11 and may even not completely report the onset of the
12 condition. And for that reason Glastetter found that case
13 reports are not scientifically valid proof of causation.

14 That's consistent, of course, with the Eleventh
15 Circuit in the Rider case. It's consistent with this
16 District in the Willert case, and the Polski case. And so
17 if all we're left with are case reports, that is not a
18 reliable basis, not a reliable methodology for Plaintiffs to
19 point to.

20 In sum, the Court has to look behind just the
21 rhetoric of the briefing here and look at the evidence that
22 has been presented to the Court and compare it to the
23 Daubert factors. On testing, the experts have provided the
24 Court with no epidemiology supporting causation between
25 Viagra and NAION.

1 I should address briefly the subgroup they point
2 to. In Dr. McGwin's study there is a small group of men, we
3 don't know how small, but a small group of men who had a
4 prior history of myocardial infarction; and in that
5 particular subgroup Dr. McGwin reports to have found a
6 statistically important finding. But it's important to
7 understand how Dr. McGwin reached that result. And if you
8 can give me one moment, your Honor.

9 In the course of his study Dr. McGwin collected
10 data on various characteristics, nine different
11 characteristics of the people participating in the study.
12 And after the study was concluded and after he found no
13 statistically significant overall association, he went back
14 and looked at the individual characteristics to see what he
15 could find. And in eight of those nine subgroups Dr. McGwin
16 did not find a statistically significant association.

17 In one, the one with patients with prior
18 myocardial infarction, Dr. McGwin found a statistically
19 significant rate. But Dr. McGwin acknowledged that there
20 were problems with this methodology.

21 "Q. And, in fact, if you partition a set of data
22 into small subsets, you make it more likely that some subset
23 will show a statistically significant difference even if
24 there's no real underlying difference, correct?

25 A. Yes, sir.

1 Q. And indeed, if you test enough subgroups, a
2 false positive result will emerge from the data purely as
3 the result of chance, correct?

4 A. Will result or can result?

5 Q. Yes. Will result. If you test enough
6 subgroups?

7 A. If you test enough subgroups, yes, sir.

8 Q. You're going to get it, right?

9 A. Yes, sir."

10 In other words, the more you slice up the data,
11 the more likely you're going to find some statistically
12 significant result even if that result is, in fact,
13 meaningless.

14 At Dr. McGwin's deposition he recognized that the
15 epidemiological community treats this analysis of subgroup
16 results as surprisingly unreliable. And in his report
17 Dr. Kimmel, Pfizer's epidemiology expert, gave an actual
18 example in this case in this published article from Jama,
19 Yusef, Analysis and Interpretation of Treatment Effects in
20 Subgroups. The author refers to a study that show that
21 people who take aspirin have a lower rate of heart attack.
22 But when you analyze that information by Zodiac sign, they
23 found that people with Libra -- who are Libra and Gemini
24 were in fact suffering harmful effects from aspirin.

25 Now, that obviously is a spurious result and it's

1 for that very reason that the authors said that this type of
2 reliance would hardly be expected to provide reliable
3 estimates of treatment effect.

4 And even Dr. McGwin acknowledged in his deposition
5 that this type of analysis is a scientifically flawed
6 methodology. So we can't point to the subgroup as somehow
7 evidence of a larger association or even of association in
8 this very subgroup. And even if we could, Dr. McGwin
9 recanted his reliance on that subgroup. In his report he
10 wrote, as your Honor has seen, that the author has reported
11 an odds ratio of 10.7 in this subgroup. But when he was
12 asked about it in his deposition:

13 "Q. Okay. And contrary to what that sentence
14 says or that portion of the sentence says, in your article,
15 you report no odds ratio data for men who reported Viagra
16 use alone and had a history of myocardial infarct, correct?

17 A. That's correct, yes.

18 Q. So that sentence is wrong?

19 A. Yes, that's correct."

20 And that's the only testimony under oath about
21 this subgroup. And Dr. McGwin didn't change his testimony,
22 Plaintiffs didn't ask him to clarify this testimony. And
23 even though we raised this in our opposition to Plaintiffs'
24 motion, Dr. McGwin put in an affidavit in reply to that
25 opposition, he never attempted to change this testimony.

1 Also, the third reason they can't rely on this
2 subgroup is that they have waived the reliance. We asked
3 for the underlying data to support the subgroup analysis and
4 Rule 26 requires disclosure of the underlying data that the
5 expert relies on. And Plaintiffs refused to provide that
6 information. The Eighth Circuit in the Mems versus City of
7 St. Paul case affirmed the District Court's exclusion of an
8 expert who did not disclose the data he had collected
9 underlying his opinion.

10 And finally, an epidemiological result, at most,
11 gives you an association whether there's a statistically
12 significant finding. You have to take in an association and
13 compare it to everything else in order to turn it into
14 causation. And not a single one of the experts points to
15 this subgroup and uses that as the foundation of any type of
16 causation analysis. In fact, as we saw earlier, the three
17 other experts universally agree that there's no epidemiology
18 evidence to support the experts' opinions in this case.

19 Your Honor questioned whether -- questioned my
20 cite to Daubert and whether Daubert says that if a theory
21 can't be tested that it's not admitted. This is what
22 Daubert says. And if I can turn this on, I can even put it
23 up on this.

24 There we go. This is, again, this is from the
25 Supreme Court's decision in the Daubert case. And at 593

1 the Court says: "Ordinarily, a key question to be answered
2 in determining whether a theory or technique is scientific
3 knowledge that will assist the trier of fact will be whether
4 it can be (and has been) tested. 'Scientific methodology
5 today is based on generating hypotheses and testing them to
6 see if they can be falsified; indeed, this methodology is
7 what distinguishes science from other fields of human
8 inquiry.'" And citing the Hempel article. "The statements
9 constituting a scientific explanation must be capable of
10 empirical test." Including from another article, "The
11 criterion of the scientific status of a theory is its
12 falsifiability, or refutability, or testability."

13 And absent the ability to test, that is a reason
14 to exclude the opinion, not to let it in.

15 So, again, coming back to the Daubert factors, on
16 testing the experts have provided the Court with no
17 epidemiology, with no animal testing, with no clinical
18 testing, and no testing of the critical foundation of
19 Dr. Hayreh's theory. What is out there are three studies,
20 three epidemiological analyses, which fail to demonstrate an
21 increased rate of NAION. Ten blood flow studies which test
22 as close as we can get to the optic nerve and find no
23 decrease in blood flow, and every other study that has been
24 done looking at blood flow anywhere in the body which fails
25 to find any decrease in flood flow in any part.

1 Look -- going back to Daubert, peer review and
2 publication, the only article that Plaintiffs can cite is
3 Dr. Hayreh's viewpoint and that article suffers from the
4 same foundational flaws as his expert report here. There's
5 no original research supporting it. It's simply his
6 theories.

7 Finally, widespread acceptance, Plaintiffs have
8 put forth no evidence that the views of their experts have
9 gained widespread acceptance in the medical community. And
10 again, the evidence that exists is to the contrary. The FDA
11 has found it's not possible to find -- determine a causal
12 relationship. The published scientific articles that we
13 cite in our brief, they have concluded that a causal
14 relationship cannot be established. Plaintiffs' own expert,
15 Dr. Pomeranz, has published numerous articles and given a
16 presentation to his own scientific peers which describe the
17 relationship between Viagra and NAION as unclear and
18 controversial. With that lack of evidence, there is simply
19 no reliable methodology underscoring the Plaintiffs'
20 expert's positions.

21 Unless the Court has further questions on our
22 motion, I'm just going to use a little bit of my time to
23 just address a couple of points on Plaintiffs' motion, and
24 I'll reserve the rest of it for after.

25 THE COURT: Sure.

1 MS. LESKIN: Plaintiffs have raised the
2 qualifications of Pfizer's experts. Dr. McGwin acknowledges
3 that Dr. Kimmel is well-known, a talented, respected
4 pharmacal epidemiologist. In fact, he has written one of
5 the leading textbooks on epidemiology. They don't dispute
6 both Dr. Netland and Dr. Gamel are well-qualified
7 ophthalmologists who have diagnosed and treated patients
8 with NAION. Plaintiffs' efforts to require them to be
9 certified as neuro-ophthalmologists is just simply
10 inconsistent with the factual record and the case law.
11 Their own experts have not said that you have to be a neuro-
12 ophthalmologist in order to conduct a critical analysis of
13 the literature. And all of the issues that they raise on
14 qualifications are best reserved for cross-examination
15 should we get that far.

16 They argue that our opinions are solely designed
17 for litigation. But those opinions and the methodology used
18 is consistent with the published literature which, as we
19 discussed, finds that there's no substantial evidence,
20 there's no reliable evidence of a causal association. And
21 where the opinion uses reliable methodology and is
22 consistent with the published literature, Daubert does not
23 require that that -- those opinions be excluded. To the
24 contrary, they do have a fundamentally reliable basis.

25 Plaintiffs have continued to shift the burden of

1 proof and mischaracterize the very opinions of the experts'
2 reports. None of our experts have offered an opinion that
3 Viagra does not cause NAION and that is not our burden. The
4 question here on both motions, and in this case, is whether
5 there's reliable methodology to support an expert opinion
6 that Viagra can cause NAION. And our experts have done a
7 critical review of the literature that exists and found that
8 there is no reliable evidence to support such a question.

9 Plaintiffs have spent a lot of time complaining
10 that the Gorkin article is not actually a study. Well,
11 whether we classify it as a study, analysis, a
12 epidemiological review, it's all besides the point. The
13 bottom line is that study, that article, does not provide a
14 foundation, does not provide a reliable basis for an opinion
15 that Viagra causes NAION. And Plaintiffs' own experts have
16 acknowledged that fact.

17 Finally, Plaintiffs have pointed in their reply
18 brief to some testimony from Dr. Gamel --

19 THE COURT: Before you go on to that.

20 MS. LESKIN: Absolutely.

21 THE COURT: You just made a reference to something
22 that I struggled with and that's in one sentence. A couple
23 of sentences ago you made the reference to the fact that
24 there was no evidence that Viagra can cause NAION. And then
25 you came back in the next sentence and said that there's no

1 evidence that it does cause NAION. Now, there's a
2 difference between those two phrases.

3 MS. LESKIN: I grant you that.

4 THE COURT: Okay.

5 MS. LESKIN: And the question is?

6 THE COURT: What's your position on the
7 difference?

8 MS. LESKIN: Well, the question here, your Honor,
9 is general causation, is Viagra capable, can it cause NAION.
10 And Plaintiffs have to -- Plaintiffs' burden at this time is
11 to come forward with reliable expert evidence with a
12 sufficient scientific foundation that Viagra is capable of
13 causing NAION. And you need to look at the underlying
14 science that they point to to determine if that's the case.
15 And whether I misspoke and said does, certainly the evidence
16 does not show -- the reliable evidence does not support a
17 conclusion that Viagra can cause NAION. And that is the
18 question that we have to look at here.

19 But Dr. Gamel, they cited to you, has a statement
20 in his deposition as to whether it was possible. Going back
21 to what we were talking about before and Dr. Hayreh's
22 theory, whether the studies that look at this vessel show a
23 decrease or no increase, whether it's possible for another
24 vessel further downstream to show a decrease in blood flow.
25 And they pointed to some testimony from Dr. Gamel, our

1 expert, to say that that was possible.

2 But you have to look at Dr. Gamel's testimony to
3 understand what he was referring to. So when we spoke --
4 when I asked him, this is how he explained that:

5 "Q. Under what circumstances could that happen?

6 A. The only physiological circumstances that I'm
7 aware of would be -- where it's been proven, would be
8 vascular obstruction.

9 Q. And in the absence of a vascular obstruction,
10 does it make physiological sense, based on your knowledge of
11 anatomy and physics and physiology, in the absence of a
12 vascular obstruction, does it make physiological sense for
13 there to be an increase or no change to blood flow in the
14 ophthalmic artery, and a simultaneous decrease downstream in
15 the vessels that feed the optic nerve?"

16 Again, that's this vessel.

17 "A. That is not consistent with my understanding
18 of the flow of physiology involved in that system and I'm
19 certainly not aware of it -- I cannot imagine where it might
20 happen short of embolus.

21 Q. Again, in the absence of an obstruction or
22 embolus?

23 A. In the absence of an obstruction, that's
24 correct.

25 Q. Does it make physiological sense for there to

1 be an increase or change in blood flow to the posterior
2 ciliary arteries and yet a decrease in blood flow?

3 A. It makes sense in an obstructive situation
4 which could be an embolus or thrombus.

5 Q. And absent that, does it make sense?

6 A. I'm not aware of any physiologic process where
7 that can occur. I'm not aware of it and I can't -- well, I
8 can't -- I don't know of any process and I can't imagine
9 one.

10 Q. And, again, in the absence of an obstruction
11 via thrombus or an embolism, does it make physiological
12 sense for there to be an increase or no change in blood flow
13 to the PCA -- "

14 That's these.

15 "-- yet have a decrease in the flow to the optic
16 nerve?

17 A. No. Barring an embolic event, no."

18 It's undisputed, and Dr. Hayreh acknowledged, that
19 NAION is not an embolic or a thrombotic event. So
20 Dr. Gamel's testimony does not help the mechanism here.

21 And unless the Court has any other questions, I'm
22 going to reserve the rest of my time, your Honor.

23 THE COURT: Okay. Thank you very much.

24 Mr. Becnel, do you want to do the change around
25 first? Do you want to take a five-minute recess to unhook

1 and rehook?

2 MR. BECNEL: That would be a good plan.

3 (Recess taken from 10:28 to 10:34 a.m.)

4 MR. BECNEL: May it please the Court.

5 THE COURT: Good morning, Mr. Becnel.

6 MR. BECNEL: I think the Court has to understand a
7 few of the facts of this drug to help understand the Daubert
8 issues. This drug was not a drug that was developed by
9 hypothesis such as a new life-saving cancer drug or leukemia
10 drug. This was a drug developed for angina.

11 They had a trial going on in England between men
12 and women. A gentleman Ph.D. by the name of Peter Ellis was
13 doing the trial and conducting the clinical trial. All of a
14 sudden after a year or so he found no absolutely no benefit
15 to the drug concerning angina. So then he asked all of the
16 participants in the study, men and women, to give him the
17 drug back, and as a result of that the women all gave him
18 the leftover drugs. None of the men did. They flushed it
19 down the toilet, threw it away, didn't have it. He digs
20 deeper into it and he finds out, All of a sudden I realized
21 I had a eureka moment. These men were having erectile
22 dysfunction prior to, but with the drug it helped. That's
23 it. No studies are done at that time dealing with that. It
24 was only after his eureka moment that they started doing
25 studies.

1 Now, why is this case here and how did it develop?

2 A physician named Dr. Pomeranz, who was a partner of
3 Dr. Neil Sherra (phonetically spelled) here in Minnesota,
4 started seeing some of these case studies. People came to
5 him not from lawyers, not from litigation, not from
6 advertisements, not from anything but referred to him from
7 physicians, and he developed a few case studies.

8 Dr. Hayreh, who invented the term NAION, with over
9 50 years of research, probably has treated more of these
10 people than anybody in the world combined, he was tried to
11 be hired on two or three different occasions by Pfizer and
12 he refused. He didn't even talk to Plaintiffs before his
13 deposition or Plaintiffs' lawyers, and refused to take cases
14 except from physicians who referred them to him and, believe
15 it or not, in Iowa City, Iowa, which we subsequently learned
16 was one of the leading eye centers in the world.

17 In any event, he testified that, Look, you can't
18 study cats, you can't study dogs. The only thing that you
19 can study to deal with this is monkeys. And he has done
20 more monkey studies than anybody else dealing with it.

21 So the five patients that he first came up with,
22 Dr. Pomeranz did, and then seven subsequent patients, none
23 of whom were sent to him by lawyers, were involved in
24 litigation. This case came to you because of Mr. James
25 Thompson. This is Mr. Thompson. He is an engineer. He

1 filed suit against -- this is from CNN when he started
2 disclosing that he took Viagra, went to bed, and woke up and
3 not totally blind. You have to understand this thing
4 happens, it's like you taking a lens out of your eyeglasses
5 and you wake up in the morning. You really don't realize
6 one of the lenses are missing until you start trying to read
7 and then you realize it later in the day.

8 Mr. Thompson is probably from one of the more
9 affluent areas in Houston, Texas, and can't see. Some
10 people have it in one eye, some people have it in a third of
11 an eye or half of an eye. Some have a little bit here and
12 there and challenge-rechallenge, they took it again and they
13 lost the rest.

14 My two colleagues are going to address specific
15 issues. Mr. Hopper will deal with the main Daubert issues
16 and Mr. Overholtz will deal with all of the issues related
17 to the science and the experts.

18 THE COURT: Okay. Mr. Becnel, if -- I know that
19 there's a plane that you have a finite time to catch.

20 MR. BECNEL: I have one for 1:50.

21 THE COURT: And if we're staying on and you need
22 to leave, you're excused. And by the same token if your
23 phone goes off and you have to leave, feel free to leave.

24 Okay. Mr. Hopper.

25 MR. HOPPER: If it please the Court, your Honor,

1 I'm Randy Hopper, Zimmerman Reed law firm, on behalf of the
2 Plaintiffs here today. When we all started this case,
3 admittedly everyone had to confess to some extent that this
4 is not such an easy topic to discuss. It's a little bit
5 uncomfortable sometimes even as professionals to talk about
6 erectile dysfunction and these kinds of issues, perhaps even
7 more so for men to talk about it. But obviously we're here
8 as professionals and as Plaintiffs' lawyers it's our job to
9 represent men who took Pfizer's drug and were injured by it.
10 That's what we cannot lose sight of.

11 Even in a Daubert motion, your Honor, where we're
12 swimming with all of these facts and figures and scientific
13 and medical terms and parlance, we can't lose sight of the
14 fact that even though perhaps the population of men is
15 small, these men experienced real injuries, many within 24
16 to 48 hours of ingestion of the drug. Those are issues for
17 merits that your Honor will have an opportunity to examine
18 more carefully if in this Court's wisdom you allow us to
19 proceed and our experts to present testimony to the jury as
20 they should be allowed to do.

21 But these men experienced real injuries, as
22 Mr. Becnel alluded to, with lost or impaired vision. That's
23 the subject of the lawsuit, your Honor. Not sexual
24 impotency but vision loss and impairment caused by Viagra.

25 Plaintiffs' experts are eminently qualified to

1 testify to causation. They are leaders in their field,
2 particularly in neuro-ophthalmology. And it's important and
3 it's worth noting, the Defendants haven't even proffered
4 neuro-ophthalmologists among their cache of experts. For
5 some reason they haven't been able to bring forth
6 neuro-ophthalmologists which, as Ms. Leskin showed the Court
7 specifically, is the gambit within which this injury and
8 this disease falls. It's about blood flow and it's about
9 profusion of blood flow. But it has to do with the retinal
10 nerve. And the neuro-ophthalmologists, like the vascular
11 surgeons over in the subsets of heart surgery of the
12 cardiologists and even the thoracic surgeons, these are the
13 subspecialists that understand this disease. These are the
14 subspecialists who understand the nuances of this.

15 Plaintiffs have proffered two
16 neuro-ophthalmologists eminently qualified, particularly in
17 ophthalmology. They are medical doctors and scientists who
18 have conducted research, ophthalmologic research on NAION,
19 AION and ION, and have indeed diagnosed and treated NAION,
20 AION and ION in patients they have seen.

21 These ocular blood flow injuries are nothing new.
22 What we're seeing now is a toxic relationship of a drug
23 which I don't think Pfizer even knew when they tested it and
24 brought it to market -- that's an issue of liability that
25 we'll discover on merits -- knew that there was a

1 possibility of this causation, which is why I don't think
2 they can put up the experts to defend themselves on a
3 Daubert challenge.

4 In the case of Dr. Hayreh, your Honor, he's the
5 man -- he is the doctor, he is the scientist who discovered
6 NAION. If anyone, if anyone in the world knows and
7 understands NAION, he does in no uncertain terms. These
8 experts that Plaintiffs have brought forward have rendered
9 their opinions not for purposes of this litigation. They
10 have not speculated wildly, as the fringe issues bring
11 forward in the Daubert decisions and the progeny of cases
12 from Daubert, to show why an expert's testimony is not
13 allowed. They have not invented the bases for their
14 opinions for purposes of this litigation. They have not
15 created this out of whole cloth and just coming up with this
16 idea so they could help some Plaintiffs' lawyers.

17 These are experts eminently qualified who have
18 studied -- and I'll grant, since Ms. Leskin brought it
19 forward, but I think there's an important distinction to
20 understand as your Honor recognized from the bench a moment
21 ago in trying to understand Daubert, it says testing, I-N-G,
22 testing. Not tested, not to final conclusion. Daubert is
23 not about conclusions. Daubert has standards relating to
24 relevancy and to reliability.

25 I'll talk briefly in the main about the

1 Plaintiffs' experts and why they meet the factors enunciated
2 in Daubert v Merrell. Then my colleague and co-counsel, as
3 Mr. Becnel mentioned, Mr. Overholtz, will amplify on these
4 points to show the Court more precisely why Plaintiffs'
5 experts should not be disqualified and why in fact they come
6 within and meet the standards of Daubert and should come
7 forward to meet the jury.

8 And finally I intend, more for the record than for
9 any other reason, to touch on the key points of Daubert,
10 even though Ms. Leskin has done that, and of Rule 702. What
11 those address and perhaps, your Honor, what they do not.

12 Daubert and Rule 702 briefly, your Honor, the
13 rules and the case law are very clear that this Court is
14 given wide latitude when applying Daubert in the context of
15 expert testimony. And certainly, your Honor, I don't need
16 to take up a lot of the Court's time. This Court is
17 exceedingly experienced with the Daubert motions and Daubert
18 issues. And, your Honor -- but as your Honor knows, in its
19 role as gatekeeper, the District Court exercises its
20 authority for insuring that an expert's testimony simply
21 rests on a reliable foundation and relevant to the task at
22 hand. And the task at hand is the profusion of blood flow
23 that you're going to hear about from Mr. Overholtz. That's
24 where the science focuses. That's where the
25 neuro-ophthalmologists bring forth their testimony that's

1 both relevant and reliable.

2 In short, your Honor, a trial judge, as Daubert
3 further enunciates, a trial judge in applying the standards
4 of 702 and 104a must make a preliminary assessment of
5 whether the expert's testimony and underlying reasoning and
6 methodology is scientifically valid and can properly be
7 applied to the facts of the case. If the testimony is found
8 to be scientifically valid and is proper for the facts of
9 the case, the testimony is deemed admissible.

10 And to meet the Daubert standard of reliability
11 and of relevance, as I mentioned and as codified in Rule
12 702, in addition to these threshold requirements of
13 relevance and reliability, Daubert has certain nonexclusive
14 factors. The nonexclusive factors to be considered in
15 deciding a Daubert motion on proposed scientific testimony
16 as to whether it's good science include whether the theory
17 can be tested, whether it has been subjected to peer review
18 and publication, is there a known or potential rate of error
19 in scientific technique, and the general acceptance of the
20 theory or technique in the relevant scientific community.

21 In addition to these, the Eighth Circuit has
22 recognized additional factors: Whether the expert testimony
23 was developed purely for litigation or did it naturally flow
24 from the expert's own experience, clinical research, bench
25 research, testing and hypothesis that they put forward; and

1 whether the expert ruled out other alternative explanations,
2 and whether the proposed expert sufficiently connected the
3 proposed testimony with the facts of the case.

4 That's exactly, precisely, what our experts have
5 done here, your Honor, to fulfill the Eighth Circuit's
6 threshold's requirements.

7 Ms. Leskin's attempt to distinguish Bonner, your
8 Honor, fails. If the Court would listen for a moment to
9 Bonner, when Judge Wollman wrote: "Likewise, there's no
10 requirement that published epidemiological studies
11 supporting an expert's opinion exist in order for the
12 opinion to be admissible." But prior to that Judge Wollman
13 wrote: ". . . if there are good grounds for the expert's
14 conclusion, it should be admitted. . ." The District Court
15 should not exclude scientific testimony simply because the
16 conclusion was novel. If the methodology and the
17 application of the methodology were reliable, expert
18 witness's methodology, rather than their conclusions, is the
19 primarily concern of Rule 702."

20 And your Honor knows intimately that that's
21 directly on point with Kumho Tire from many decisions that
22 this Court has rendered. We don't have to have a
23 epidemiological study at this phase of the case in the
24 causation discovery in order for our experts to move
25 forward. We have to show that the neuro-ophthalmologists

1 and the other experts that we have engaged in that rigor.
2 That these are qualified experts who know how to engage in
3 that rigor and come to a result, but they don't have to
4 prove it conclusively.

5 Without equivocation, your Honor, we'll show and
6 Mr. Overholtz will discuss that Plaintiffs' experts both,
7 Dr. Hayreh and Dr. McGwin, as well as Dr. Pomeranz and
8 Dr. Aruna's testimony, meets the Daubert 702 standards with
9 aplomb.

10 As the Kumho Court has now stated, the objective
11 is to make certain that an expert, whether basing testimony
12 upon professional studies or personal experience, employs in
13 the courtroom the same level of intellectual rigor that
14 characterizes the character of experts in the relevant
15 field. I mentioned that a moment ago. To be admissible the
16 opinion must be reasonably based in good science. The
17 analogy, inferences and extrapolations connecting the
18 science to the testimony must be of a kind that a reasonable
19 scientist or physician would make outside the context of
20 litigation. And there's ample support for that in the case
21 law. And Ephedrine, your Honor, in PPA litigation,
22 Plaintiffs' experts certainly do all of that, your Honor,
23 here. But certainty is not the issue. Reaching scientific
24 certainty is not what Daubert is about.

25 It's interesting, your Honor, and the Court will

1 find in the guide for medical --

2 THE COURT: Well, counsel, that statement is true
3 but it's also not a shot in the dark.

4 MR. HOPPER: Absolutely not. And, in fact, the
5 Court can find instruction, and Plaintiffs who have to bring
6 the case forward and their experts can find instruction for
7 that in the Guide for Medical Testimony in the Reference
8 Manual on Scientific Evidence when it reads: "Of course, it
9 would be unreasonable to conclude that the subject of
10 scientific testimony must be known to a certainty. Arguably
11 there are no certainties in science." And in quoting, I
12 believe, an Amici in that passage in the reference guide
13 that the Court wrote in Daubert, "Indeed, scientists do not
14 assert that they know what is immutably 'true' - they are
15 committed to searching for new, temporary, theories to
16 explain, as best they can, scientific phenomena." That's
17 why experts opine to a reasonable, reasonable, degree of
18 medical and scientific certainty, not 100 percent certainty.

19 And Ms. Leskin in -- and I would argue, your
20 Honor, is reading Daubert requiring our experts to produce
21 100 percent certainty that the conclusions must be there in
22 a test that's proffered and that's 100 percent final. And
23 Daubert simply does not require that. Daubert requires our
24 experts to go through a rigor, to go through an intellectual
25 curiosity that's consistent with the scientific method and

1 that's scientifically valid. Our experts have done that,
2 your Honor.

3 And, quite frankly, your Honor, this Court knows
4 that that's what the Daubert proceeding is all about.
5 Showing the Court that our experts' opinions are relevant to
6 the subject matter concerning sildenafil's ability to cause
7 these ocular difficulties, to showing the Court that he
8 relied upon principles of research and rigors that are
9 scientifically valid within the fundamentals of the
10 scientific method.

11 Our experts' conclusions, in fact, and the case
12 law supports that, may differ, not surprisingly, from
13 Defendant's experts' conclusions. That's also not what
14 Daubert is about. The conclusions, it's not about the
15 conclusions. The conclusions will be examined by the jury
16 if this Court in its wisdom allows them to stand, allows our
17 experts to go forward and present that testimony.

18 I go back, your Honor, to the principle for a
19 Daubert 702 inquiry referenced in the beginning. The focus
20 must be on the principles and on the methodology, not on the
21 conclusions that experts generate. It's how they get there.
22 It's who they are. It's their credentials married to the
23 work that they do to bring forward the testimony. It
24 doesn't have to be 100 percent certain. It has to be to a
25 reasonable degree of certainty. And they need to have the

1 opportunity in this case, given the injuries that a small or
2 few number of men -- etiology of medicine is such that
3 immune systems, many other differential issues can affect
4 the outcome of toxic exposure, be it through a drug or
5 otherwise.

6 THE COURT: Counsel, you're hitting on the very
7 part that's the fundamental problem that comes up and you
8 just said it. They are going to have to be prepared to
9 testify to a reasonable medical of certainty. And yet
10 you're going to put a guy on the stand that says
11 epidemiology.

12 MR. HOPPER: I understand, your Honor.

13 THE COURT: Epidemiology, you have not got
14 anything statistically here. It doesn't make it. And let's
15 face it, you are dealing with a situation of dealing with an
16 elderly population where this NAION does occur in the
17 general population. Rarely, but it does occur.

18 Now, it so happens it also, and I heard the figure
19 27 million people this morning, it does occur with a
20 population of 27 million people that has happened as well.
21 Now, at some point we've got to figure out those that it
22 happened with and those that it wouldn't happen to. That's
23 why we have experts. And we put an expert up here and the
24 expert sits and says well, it kind of, could have, would
25 have, should have, that's the kind of stuff that the Supreme

1 Court just hits you over the head and says no way. You
2 know, that's where the struggles are.

3 You got a struggle. I got a struggle. We got to
4 figure out how we get from here to there because of that.

5 MR. HOPPER: And, your Honor, everything -- and I
6 would be foolish as a counselor you've known for a long time
7 to stand here and say you're not exactly right. But I would
8 address the Court and respond this way. You are given the
9 discretion at this phase of the litigation to allow those
10 experts to come forward. We're not at merits, we're not at
11 a stage to convert this, as I would argue in many
12 respects -- and I don't certainly fault her advocacy. This
13 is not a summary judgment motion. This is not a final
14 determination of the outcome of this litigation on the
15 merits of this case.

16 THE COURT: That's true.

17 MR. HOPPER: If our experts are allowed to come --

18 THE COURT: And I agree with that because it does
19 get down to could versus medical certainty. Yet at the same
20 token, there's an element of this that I think -- obviously
21 we can't ask Rehnquist anymore, but my suspicion is that
22 when they wrote Daubert it was because they are simply
23 saying not only do we play the gatekeeper function, but we
24 play the gatekeeper function early.

25 MR. HOPPER: Absolutely.

1 THE COURT: Because we know about the price of
2 litigation.

3 MR. HOPPER: And if your Honor believes when your
4 Honor has examined the credentials, the qualifications, the
5 methodologies and the relevancy of the testimony of
6 Plaintiffs' experts at this phase of the litigation, and
7 qualifiedly determines that they ain't no juice there, not
8 to be cute, then the Plaintiffs will have to pack up their
9 bags and go home. These men who were injured are going to
10 basically have the courthouse doors slammed in their face, I
11 might add, and they won't have their day in court to allow
12 this opportunity to go forward to make that determination.

13 But then again, the case law and the Supreme Court
14 is not going to slam me or slam you based on the
15 conclusions. It's about the basis for their opinions and
16 whether they have done it within a reasonable degree of
17 scientific rigor and whether they have gotten there in a way
18 that comports with the scientific method. If experts are
19 put up -- and this Court has seen and litigations have
20 occurred where experts waltz into court and try to pull the
21 proverbial wool over the Court's eyes, that's the kind of
22 gatekeeping that I would argue that the Court looks at and
23 the Supreme Court has instructed in Daubert the earlier the
24 better.

25 This isn't one of those cases, your Honor. If

1 anything, this case is close enough that the gatekeeping
2 role of this Court should allow these experts to go forward
3 so we can test that premise further. Already even this
4 month, this month, as Mr. Overholtz will demonstrate to the
5 Court, more scientific evidence is coming forward to show
6 what the experts are proffering.

7 So I would urge the Court, and I've taken a little
8 more time but I did want to respond to Court's questions,
9 but --

10 THE COURT: We're going to hear about a monkey
11 test?

12 MR. HOPPER: I'm not doing any monkey test
13 whatsoever with an organ grinder or anything. Our brief and
14 our papers, I believe, are very strong and we stand on those
15 without any equivocation. And I believe if your Honor would
16 apply the law in Daubert in such a way that comports with
17 what the standards require, including those the Eighth
18 Circuit has brought forth, that the Court will say in its
19 wisdom that it's important on behalf of these men that are
20 affected to let this case move forward; and then we'll deal
21 with this issue on summary judgment at a later phase of the
22 Court. I thank the Court's tolerance.

23 THE COURT: Thank you, Mr. Hopper.

24 Mr. Overholtz.

25 MR. OVERHOLTZ: Thank you, your Honor.

1 May it please the Court, as your Honor knows I'm
2 Neil Overholtz here to represent Plaintiffs.

3 Your Honor asked the pivotal question during
4 Ms. Leskin's argument, which is the issue we're here to
5 decide, is whether Viagra can cause NAION and should the
6 experts who have looked at the evidence be able to testify
7 using reasonably sound scientific methodology whether it can
8 or do we have to show that it does. Ms. Leskin and Pfizer
9 would have us proving that it does. That's simply not the
10 test under Daubert.

11 As your Honor is well aware, and as Mr. Hopper has
12 eloquently stated, the central test in Daubert is relevance
13 and reliability. And when looking at the reliability, we
14 have to look at whether there is sound scientific
15 methodology followed by these experts in reaching their
16 opinions. And in this case I'm convinced that each of the
17 Plaintiffs' experts arrived at their conclusions applying
18 the sound scientific methodology, the type of sound
19 scientific methodology they apply in the course of their
20 works as experts in this field, not as litigation experts.

21 Plaintiffs experts, Dr. McGwin, Dr. Hayreh,
22 Dr. Pomeranz, all published on issues related to ophthalmic
23 disease, ocular NAION specifically, before there was ever
24 any litigation involved in this case. The Plaintiffs'
25 experts' opinions, especially Dr. Hayreh's, are based on

1 years of experience. And the Courts have recognized in this
2 District that the years of experience of an expert in
3 reaching his conclusions and in forming his opinions and
4 making reasonable diagnoses is a basis for admissibility of
5 the expert's opinions.

6 Dr. Hayreh's been studying NAION for over half a
7 century. He coined the term "NAION" as Mr. Becnel stated at
8 the beginning of the argument. The work that Plaintiffs'
9 experts practice in this field simply can't be said for the
10 Defendant's experts. I want to first talk about Plaintiffs'
11 epidemiological expert, Dr. McGwin. We spent a lot of time
12 with this attorney hearing about Dr. McGwin's opinions,
13 talking about Dr. McGwin.

14 I think it's important to point out that
15 Dr. McGwin, as your Honor is aware from his obvious careful
16 reading of Plaintiffs' briefs, that he is one of the very
17 few handful of individuals who, as epidemiologists, Ph.D.
18 epidemiologists, focus on the issue of ocular disease. As
19 Dr. McGwin has stated, that's what he does. He studies
20 ocular disease. Before this litigation ever began in 2004,
21 Dr. McGwin had published epidemiological studies regarding
22 the diagnosis of NAION and the reasonable methods of
23 diagnosis, of methods and diagnosis techniques, and which
24 ones are better techniques for other diagnoses.

25 Your Honor made a key point during Ms. Leskin's

1 argument and that is that this analysis by the Court, which
2 as we know from the decisions your Honor has published, as
3 well as the decisions from the Eighth Circuit, and from the
4 Eighth it must be applied to this case and the facts of this
5 case. The evidence that is available, the testing that's
6 available to be done, what your Honor pointed out in
7 addressing the evidence that's available.

8 And as Dr. McGwin has stated in his expert report
9 and in his testimony and in his follow-up affidavit,
10 Dr. McGwin looked at all of the available evidence in
11 forming his opinions, and all of the available evidence
12 included not just epidemiology. As Dr. McGwin stated in his
13 report, and as your Honor knows, and no one is saying here
14 that epidemiology alone can prove causation, and
15 epidemiology is not an issue of looking at causation.
16 Epidemiology is the study to look at association. And it's
17 only upon seeing these associations, examining the strength
18 of these associations, do epidemiologists, do they then
19 apply to what we are very familiar with in the study of the
20 Bradford Hill criteria and determining whether or not
21 there's a causal relationship.

22 That's exactly what Dr. McGwin has done here. He
23 has looked at all of the available evidence, the case
24 reports, the challenge-rechallenge evidence, the evidence of
25 a plausible biological mechanism. That's certainly one of

1 the factors involved in the Bradford Hill criteria. And
2 while Ms. Leskin played several small snippet clips of some
3 of her expert's testimony, including Dr. McGwin regarding a
4 definitive proven mechanism, as this Court is aware this
5 definitive proven mechanism isn't necessary for an expert to
6 be allowed to testify under Daubert. In the Baycol
7 decision, Judge Davis recently found that a definitive
8 mechanism of action isn't required. Instead it is how did
9 the expert reach those opinions? How did the expert come to
10 those fundamental conclusions? Did it reach it through an
11 application of scientific methods? In this case Dr. McGwin
12 did.

13 There's a lot of talk about the exact findings of
14 Dr. McGwin's study and the methodology of that study. One
15 thing that Pfizer cannot do is attack the methodology of
16 Dr. McGwin's study. Dr. McGwin's epidemiological study here
17 was a case control study. When you're looking at rare
18 diseases like NAION, performance of a clinical trial to sign
19 up cases and controls, give some groups the medicine, give
20 other people a placebo and then look for this event, is
21 really a waste of epidemiological time. Their own witness,
22 Sobel, testified and has written in the documents that we
23 used in the deposition of her, testified that cases of the
24 rare disease of NAION are at the rare extreme of what
25 epidemiology can do, but a case control study is the best

1 method for looking at a rare disease like NAION.

2 Not only does Dr. McGwin agree with that, the FDA
3 agreed with it. The FDA has been in negotiation now with
4 Pfizer for nearly three years to ask them to please do a
5 case control study. And I think we provided your Honor in
6 our subsequent briefing with some of the recent
7 correspondence that your Honor ordered that Pfizer produce
8 to us at the recent status conference. The European
9 Regulatory Agency agreed that a case control study like the
10 McGwin study was the best method of looking at this disease.

11 Pfizer held multiple meetings on this issue and
12 they invited experts to come and meet with them. They had
13 meetings in Ft. Lauderdale, New York, Chicago. Dr. Brian
14 Strom, one of the co-editors of the Textbook of
15 Pharmacoepidemiology text, as well as one of the co-editors,
16 Defendant's Expert Stephen Kimmel, of the other
17 epidemiological text, was one of their advisors. He is one
18 of the world's most renowned pharmacoepidemiologists. No
19 one disagrees with that. He told them that a McGwin-like
20 study is the right type of study.

21 Can you pull up number 18?

22 Dr. Strom favored the McGwin-like study as it most
23 closely resembles a definitive study. He realized it would
24 take years to complete while the other studies may be
25 relatively shorter in duration. The methodology of

1 Dr. McGwin's study is not in question here. It is the type
2 of study, the methodological study that one would perform in
3 looking at a rare disease like NAION.

4 Your Honor should know that there's some analysis
5 about how did Dr. McGwin come to these conclusions.
6 McGwin's study was not designed to look for Viagra -- a
7 relationship between Viagra and NAION. It was a sleep apnea
8 study. Dr. McGwin was studying NAION as it related to sleep
9 apnea because there had been published case reports
10 regarding sleep apnea as well whenever the McGwin study was
11 implemented. Only upon hearing of some of the case reports
12 published by Dr. Pomeranz did the McGwin team add the
13 question regarding erectile dysfunction drug use to the
14 questionnaire to see if there was any valuable information
15 to be gained. And as they reported, there were strong
16 positive associations between Viagra use and NAION in their
17 study.

18 There was a lot made about whether or not the
19 findings regarding use of Viagra overall and NAION were to a
20 statistical significance.

21 THE COURT: Counsel, there's another question I
22 have about this.

23 MR. OVERHOLTZ: Yes, your Honor.

24 THE COURT: There's a lot of -- we're talking
25 about Viagra but there's a lot of discussion in a lot of

1 these studies that are out there about the overall comment
2 relating to various erectile dysfunction drugs.

3 MR. OVERHOLTZ: Yes, your Honor.

4 THE COURT: And while they may be somewhat
5 comparable, I think they are also somewhat different. And
6 do we have anything distinguishing them as this goes on?
7 What drug we're dealing with because --

8 MR. OVERHOLTZ: There are some differences, your
9 Honor, and there are evidence regarding this entire class of
10 drugs. And these drugs are PDE-5 inhibitors and they work a
11 specific way.

12 THE COURT: But do we know in any of these things
13 which drug is specifically involved in it?

14 MR. OVERHOLTZ: What we do know, your Honor, is in
15 Dr. McGwin's study he did study the use of two erectile
16 dysfunction drugs and his conclusions are primarily derived
17 in the study itself, not his conclusions and opinions in
18 this litigation, but in that study involving the use of
19 PDE-5 inhibitor drugs. And he looked at two, Viagra and
20 Cialis.

21 We also have, and some of the documents that
22 Plaintiffs cite in their brief point to this, your Honor,
23 which is that there are case reports involving PDE-5
24 inhibitors, in fact Pfizer calls one of them -- one of
25 Pfizer's experts calls one of them a case of challenge,

1 dechallenge and rechallenge, where the event occurs again,
2 one of the strongest evidence of an association between
3 PDE-5 inhibitors and NAION that they had seen involving
4 another PDE-5 inhibitor drug.

5 The key to all of this is the pharmacological
6 properties of the drugs and how they work. They work
7 specifically on the smooth vascular cells by preventing the
8 breakdown of nitrous oxide which is what keeps our
9 vessels -- they keep the doors open so that the blood can
10 get in. But it also revolves around, and as Dr. Hayreh has
11 stated in his opinions in the testimony, around why NAION
12 occurs. And while we talk about an unproven hypothesis for
13 why NAION occurs, and there may be some disagreement in the
14 opinion, no one disagrees, and the FDA in telling Pfizer for
15 the last five years to do a study, no one disagrees that
16 NAION is caused by ischemia of the optic nerve, a lack of
17 blood profusion into the optic nerve head.

18 And that's a key difference here, your Honor. And
19 Dr. Netland agrees, Defendant's so-called blood flow expert,
20 that there's a difference between profusion and blood flow.
21 And I'm going to talk about some of the blood flow studies
22 we've seen.

23 But just to get back for a moment -- and I hope I
24 answered your Honor's question -- there is evidence about
25 all the classes of drugs that affected this. Viagra is the

1 most studied. We understand the FDA is in a negotiation
2 with the other drug manufacturers to do epidemiological
3 studies.

4 THE COURT: My question is on the studies that
5 you're proffering is whether or not there's that breakdown
6 so that the witness is going to be testifying as to Pfizer,
7 not going to be testifying as to -- well, whether it's
8 raining outside.

9 MR. OVERHOLTZ: I think that I -- that's an
10 important point and what I think what you would see from
11 Dr. McGwin testifying is that his opinions will be about
12 Pfizer and about Viagra. As to what he saw in his report,
13 he is going to tell the truth. That's the first deposition
14 the man had ever given. He is a scientist. He is going to
15 report that his study studies the result of these
16 vasodilation erectile dysfunction drugs.

17 What Dr. McGwin's study found is that Pfizer also
18 failed to mention in their briefing, and Ms. Leskin did at
19 least address it, is the extremely strong association that
20 Dr. McGwin's study found in men who had a history of
21 myocardial infarction and who have had NAION and their odds
22 of having taken an erectile dysfunction drug.

23 THE COURT: Well, counsel, that's probably right.
24 That becomes pretty easy if that were your lawsuit. Now we
25 get into epidemiological studies that go directly to

1 statistical significance.

2 MR. OVERHOLTZ: Right.

3 THE COURT: But the problem is that isn't your
4 lawsuit. It might be in one, two, three, four, five cases.
5 You know, it's in a hundred cases out here. And your
6 numbers are pretty small and I think in the study the
7 numbers are pretty small.

8 MR. OVERHOLTZ: Your Honor's point is well stated
9 in the study that the number of patients who had previous
10 myocardial infarctions are smaller than the numbers that had
11 been previously studied. It reveals this odds ratio that
12 Dr. McGwin stated that is statistically significant of over
13 10 times is borne out in the case reports. Many, many of
14 these men in these case reports and in the adverse reports
15 in Pfizer's database have a history of myocardial
16 infarction; and the same can be said for the cases before
17 your Honor here.

18 So you're right. It is part of our case, but our
19 case is broader than just patients with myocardial
20 infarction and that's why Dr. McGwin's testimony, not
21 necessarily his study, because his testimony goes beyond the
22 confines of his study. What are the reasonable
23 extrapolations that you can make as an epidemiologist from
24 the case reports, from the plausible biological mechanism
25 and from the challenge and rechallenge and dechallenge

1 evidence. We're talking about Dr. Strom.

2 Dr. Strom in his textbook admits that an example
3 of challenge/rechallenge evidence causing an event can be
4 one of the strongest evidence of causation in a particular
5 case, especially when you're involving a temporal
6 relationship.

7 Another point I think I should make, your Honor,
8 we talked about case reports. And the 27 million men who
9 have taken Viagra, one of these same advisory panel meetings
10 that Pfizer had, Dr. Strom, based on evidence that had been
11 presented by one of the other experts, indicated that there
12 was already a signal since it seemed that the incidence of
13 NAIION were already comparable from the background rates from
14 the spontaneous reports with the implication that a causal
15 relationship had already been proven. And the next
16 statement: "If the calculated incident rate has surpassed
17 the background rate, then a causal relationship had been
18 proven."

19 And what Dr. Strom was talking about was the fact
20 that the number of adverse events that were already showing
21 up in Pfizer's database seemed to match the estimated number
22 of cases that their advisors are telling them you would
23 expect to see based on the 27 million people who have been
24 using Viagra since it had been on the market.

25 And what these experts say, especially the

1 pharmacoepidemiology experts, is that there's underreporting
2 of adverse events. And the fact that there was already a
3 signal of events that were basically in line with the
4 background rate, indicated that there was -- there may have
5 already been a causal link that was definitively proven.

6 And, your Honor, Ms. Leskin talked about their
7 being three epidemiological studies and I just want to
8 briefly touch on the fact that as Dr. McGwin has stated,
9 there are only two epidemiological studies here. The Gorkin
10 paper upon which Defendant's experts rely to establish that
11 a causal link can't be ruled in, as they put it, is simply
12 the type of evidence that we have seen where the application
13 of the methodology is so flawed that it renders the
14 methodology unreliable.

15 And the key to that I think your Honor is aware
16 from reading our brief is that when they looked at their
17 clinical trial data and their study data that came out of
18 the European studies and they identified at least one
19 case -- and there's some profer that there were at least two
20 more cases in one of the studies -- they counted it as days
21 of exposure every day that a patient was enrolled in the
22 study and/or was being observed in the study.

23 And that's not how men use Viagra, and Pfizer
24 knows that's not how men use Viagra. And there was no
25 information at all from that study as to how often these men

1 took the Viagra. They may have only taken the Viagra once
2 in a six-month period. Yet in calculating the incident rate
3 to determine that it was in line with the background rate,
4 they counted every day as a day of exposure. They say maybe
5 that's just something they overlooked, and we will talk
6 about the merits more later once we get beyond the Daubert
7 hearings. But Pfizer recognized that well in advance in the
8 initial calculations they were making about how many cases
9 should we be seeing in our adverse report database.

10 Dr. Walker told them that you should only count as
11 periods of exposure maybe one day. What's the time at risk.
12 And let's go to two days because it takes about two days for
13 the drug to be eliminated from your system. To count every
14 day is simply a fundamental mistake that Dr. Kimmel bases
15 his opinions upon and it can't stand the scrutiny under
16 Daubert, nor is it relevant at all to any of Plaintiffs'
17 experts' analyses of what the epidemiological evidence shows
18 here. It doesn't predict the conclusions at all.

19 I would like next to talk about Dr. Hayreh, your
20 Honor. As Mr. Hopper and Mr. Becnel pointed out,
21 Dr. Hayreh, he is the world's leading expert on NAION.
22 While he highlights the portion that I think is relevant,
23 your Honor, they believe that -- Pfizer believed it back in
24 2000 when these reports of NAION were first published by
25 Dr. Pomeranz, they believed that Dr. Hayreh was the world's

1 leading expert.

2 And then if you look down further in the document,
3 the idea was that if they could engage Dr. Hayreh to write
4 something for us on it, if not then, have Alon write it, we
5 could preempt potential issues that could arise if this
6 group does collect a bigger series of cases. They wanted to
7 hire Dr. Hayreh, and now they want to exclude him as some
8 type of kook who has a theory that is, as some of the courts
9 have put it, as ipse dixit, not based on sound scientific
10 methodology.

11 Dr. Hayreh has studied NAION longer than anyone in
12 the world. Pfizer recognized that he was the world's
13 leading expert. And there was a lot of talk about the
14 ocular blood flow studies that Pfizer did looking at other
15 measurements. And as your Honor pointed out, you can't
16 measure in this very small tiny vasculature of the eye where
17 NAION occurs. There's not a measurement technique that's
18 good enough. And they try to extrapolate and say that you
19 can extrapolate from those ten studies whether or not Viagra
20 would play a role in NAION, and that's what their experts
21 attempt to do in this case. The truth is, your Honor,
22 that's simply not true.

23 The ten studies that Ms. Leskin talked about
24 involved some techniques for measuring blood flow that
25 Pfizer used and relies upon these ten studies, and these

1 techniques basically fall into three categories which is
2 laser Dopplar, which measures not flow of blood, not
3 profusion of blood, which are the key issues in this case,
4 but instead measures velocity of blood flow. And because of
5 the limitations of using that technique to actually measure
6 blood flow, especially in this area of the body, Pfizer
7 concluded that -- this was a document from Pfizer's files
8 and this is what they provided to the European regulatory
9 agencies that asked can't we do some blood flow studies to
10 look at this. And they told the FDA that therefore it was
11 later unlikely that any decrease in blood flow to the
12 post-laminar short posterior ciliary arteries to the optic
13 nerve head would be detectable using this technique.

14 Color Dopplar ultrasound is the other type of
15 study and that also has a problem because in order to
16 accurately measure the blood flow and the velocity of the
17 flow it has to be at a correct angle. And it's also subject
18 to other flows of blood in the eye. And Pfizer states:
19 "Moreover, there is no way to determine the vessel diameter
20 such that it is impossible to relate a change in blood
21 velocity to a change in profusion." These studies don't
22 have anything to do with profusion and that's what this case
23 is about is profusion to the eye. And profusion is the
24 amount of blood that feeds the tissue so that it doesn't
25 die. And that's what Dr. Hayreh's testimony focuses upon.

1 And Dr. Hayreh's testimony regarding profusion,
2 contrary to what Pfizer says, has been tested, has been
3 tested over and over again for all of the years Dr. Hayreh
4 has been studying this issue. It's based on simple physics
5 and those physics are that Viagra causes drops in blood
6 pressure. No one disagrees that it's a vasodilator. In
7 certain patients it causes drops in blood pressure and in
8 their clinical trials they had many patients that had to
9 drop out because of events that caused their blood pressure
10 to drop too low. And they also recognized that in the
11 presence of certain types of nitrates that the drops in
12 blood pressure would be extremely significant. And that's
13 why that's in the product labeling and the FDA required them
14 because their clinical trials showed that when used with
15 nitrates, blood pressure would drop significantly. That's
16 because nitrates work as a similar type of vasodilator.

17 THE COURT: What happens, I'm curious, you
18 mentioned nitrates. How many people get NAION when they
19 overdose their nitrates when they think they are getting a
20 heart attack?

21 MR. OVERHOLTZ: As Dr. Hayreh has stated, no one
22 has really studied the prevalence of NAION associated with
23 nitrate use. But there is something to be gleaned from that
24 and it's part of Dr. Hayreh's complaint.

25 THE COURT: I'm not sure if it has anything to do

1 with anything.

2 MR. OVERHOLTZ: Well, it does. The methodology of
3 Dr. Hayreh reaching his opinions, which are reasonable
4 deductions, which this Court and in Bonner and US Xpress has
5 recognized an expert may make reasonable deductions from the
6 known science and the known facts. Most patients do not
7 take nitrates at night before they go to bed for chest pain.
8 Most patients don't take blood pressure medication at night.
9 In fact, physicians wisely advise them not to take blood
10 pressure lowering medications at night and that's because of
11 this syndrome known as nocturnal hypotension which is the
12 other fundamental brick in Dr. Hayreh's theory.

13 Dr. Hayreh has studied men with NAION, hundreds of
14 men with NAION, and has done clinical studies involving
15 measuring their effects on blood pressure at night and has
16 determined that a majority of men who have suffered NAION
17 suffer from nocturnal hypotension.

18 THE COURT: How about women?

19 MR. OVERHOLTZ: I don't know that he has studied
20 women or not, but he may have studied women as well because
21 this is not an event that just affects men. It does affect
22 women, too. But in persons that Dr. Hayreh has studied that
23 he has determined that they have nocturnal hypotension.

24 And I talked to you about the bricks of
25 Dr. Hayreh's theory. They are bricks. Nocturnal

1 hypotension causes significant drops in blood pressure in
2 certain patients. It's associated with NAION. And the
3 mechanism is the fact that there is an ischemic event to the
4 eye. A drop in blood pressure.

5 And how do we know that there be can be a ischemia
6 caused by a drop in blood pressure? It's a simple physics
7 theory that Dr. Netland recognized. Their expert that
8 authored two or three theories in his original manuscript
9 recognized this. Even their replaced expert in a
10 publication that came out just this month in the issue of
11 Glaucoma Today recognized that perfusion pressure is the
12 difference between what your normal blood pressure is, your
13 main circulatory pressure, and the pressure within the eye.
14 And if either your blood pressure goes down or your pressure
15 in your eye such as in glaucoma patients goes up, you can
16 have a reduction in perfusion.

17 And that is a tested theory. Ocular perfusion
18 pressure can therefore be defined as the difference between
19 arterial blood pressure and the IOP, interocular pressure.
20 It is calculated by taking two-thirds of the mean arterial
21 pressure and subtracting the IOP.

22 This same physics principle recognized by Dr. Alon
23 Harris -- Defendant's last blood flow expert, nonmedical
24 doctor blood flow expert, who now Pfizer has attempted to
25 replace with a medical doctor blood flow expert who still is

1 not a neuro-ophthalmologist -- that same theory, physics
2 theory, is right in the center part of Dr. Hayreh's report
3 and his published literature regarding NAION that was
4 published before this litigation ever began.

5 Further, Dr. Alon Harris recognized Dr. Hayreh's
6 theory that patients that experience large fluctuations in
7 blood pressure at night may have a higher risk of glaucoma
8 regression compared with individuals whose blood pressure
9 fluctuates within normal limits. Glaucoma causes blindness,
10 too.

11 And it should be noted that Dr. Harris and
12 Dr. Netland, their new expert, is not an MD but rather a
13 Ph.D., and Plaintiffs have been unable to identify any case
14 where the Court has allowed a party to substitute a
15 nonmedical expert for a medical expert. They may exist. We
16 found no case law supporting such a substitution. But
17 should the Court allow the substitution, the fact that Dr.
18 Harris has recognized that nocturnal hypotension plays a
19 role in how glaucoma causes blindness the same way NAION
20 causes blindness by restricting blood flow and creating
21 ischemia to the optic nerve, it's about blood profusion and
22 that's the central basis of Dr. Hayreh's theory and it is
23 supported by science and tested theory and reasonable
24 deductions from the known science.

25 I'd like to read to your Honor what Pfizer told

1 the European Regulatory Agency about these ten studies. The
2 European Regulatory Agency wanted them to do more studies as
3 well. And it says: "This document addresses the
4 inadequacies of currently available methods to measure
5 circulatory beds involving NAION. It is concluded that
6 reproducing in patients studies of the effects of sildenafil
7 on retinal blood flow previously performed in normal
8 subjects would have no relevance to the risk of NAION."

9 This is Pfizer telling the European Regulatory
10 Agency these things have no relevance to the risk of NAION.
11 "They are insensitive to changes in the flow of the
12 post-laminar nerve."

13 And then they were talking about the color Dopplar
14 type studies. "Without a means of estimating vessel
15 diameter, the relationship between velocity and blood
16 profusion will be unknown. Thus, color Dopplar is of no use
17 in assessing NAION risk." No use in assessing NAION risk.
18 Yet they would have us believe that Dr. Hayreh is telling
19 them that these studies are irrelevant and not important and
20 that their experts' reliance on those ten ocular blood flow
21 studies, and then the leaps of faith that Daubert does not
22 allow, that somehow that if you can just, because they
23 showed no change of blood flow where they could measure,
24 that there would not be a change in profusion downstream,
25 those are simply leaps that science doesn't allow.

1 THE COURT: Counsel, I think I should warn you
2 that I think we're down to about five minutes.

3 MR. OVERHOLTZ: Let me wrap up then. Your Honor,
4 they talked about Dr. McGwin's application of the Bradford
5 Hill criteria and also as well, obviously, Dr. Aruna about
6 there being no animal studies.

7 First, let me tell you that Pfizer told the FDA
8 when they were talking, when the FDA asked them to do animal
9 studies, that they were not aware of animal models that
10 could reproduce the effects of NAION at all, and that was at
11 the -- at the time of the testimony in this case that Dr.
12 McGwin gave. So when Dr. McGwin testified that there wasn't
13 an experimental model, there wouldn't be an experimental
14 model. No one was aware of a valid animal model to report
15 on the effects of NAION.

16 But in the last week a new study, a pig study --
17 if your Honor will allow us along with a couple of new
18 studies from Dr. Harris that we could file with Court as
19 evidence in the case a new study involving pigs -- people
20 who study blood flow for a living have now discovered that
21 it very well may be that beyond the effects of Viagra has
22 with causing systemic drops in blood pressure, that it may
23 actually affect the receptors in these actual arteries,
24 these post-laminar arteries and this post-ciliary artery,
25 this post-laminar optic nerve in the same way. That the

1 PDE-5 inhibition could actually result in a drop in
2 profusion of blood to the optic nerve because of the direct
3 action of sildenafil.

4 So, you know, animal studies have come forward
5 that do support the theories of Dr. Hayreh, Dr. Aruna and
6 Dr. McGwin. But of course at the time Pfizer recognized
7 that there were no such animal studies.

8 MR. BECNEL: You got copies of this, Neil, to give
9 to both the Court and counsel?

10 MR. OVERHOLTZ: I think the copies are over there.

11 MR. BECNEL: We'll provide them.

12 MS. LESKIN: You mean the studies that you were
13 introducing that no experts have relied on? We do not have
14 copies of those.

15 MR. OVERHOLTZ: Well, it just came out this week,
16 your Honor. I don't know if we have the hard copy of that
17 document. We just got it off the Internet last night.

18 I want to conclude, before I reserve a small
19 amount of time, Pfizer hired someone to review the adverse
20 events reports in their database, Mitch Brigell. And
21 Mr. Brigell, who was a Ph.D. in psychology, who had worked
22 in ophthalmology issues for Pfizer, he narrowed his focus of
23 the over 160 reports that were in Pfizer's database to those
24 that had a strong temporal relationship and identified cases
25 where the event had occurred with less than 12 hours. And

1 there were many of those cases identified in his report.

2 And he further went through a causal analysis of
3 each one and in multiple reports. Dr. Brigell makes an
4 analysis of whether or not it was related to the NAION. And
5 many of the cases in which he determined that the diagnosis
6 was either possibly or probably NAION, he determined that it
7 was possibly related.

8 The fact that Pfizer's internal expert would reach
9 a different conclusion than Plaintiffs' experts looking at
10 the same evidence is not surprising, but it's not a basis
11 for excluding Plaintiffs' experts. Plaintiffs' experts
12 looked at this same evidence and concluded that based on all
13 of the evidence that was available to them, that there was a
14 causal relationship and that Viagra can cause NAION.

15 Your Honor, just to briefly touch on Dr. Aruna.
16 Dr. Aruna is a pharmacologist. He provided a standard of
17 cases. Pfizer believes that Dr. Aruna jumped to the
18 conclusion that there was a causal relationship identified
19 in the literature between NAION and Viagra. That's simply
20 not true.

21 Dr. Aruna as a pharmacologist, as noted in
22 Dr. Strom's text, that challenge/dechallenge evidence is one
23 of the strongest pieces of evidence available. And to him
24 that was evidence enough combined with the epidemiology and
25 the other case reports that he was able to do a case

1 specific analysis of Mr. Thompson, whose pictures you saw at
2 the beginning of this presentation.

3 And Dr. Aruna doesn't rely upon his case specific
4 analysis of doctor -- of Mr. Thompson. Instead, what
5 Dr. Aruna relies upon is all the evidence available. And he
6 illustrates to the Court that in applying those -- that
7 knowledge, you can apply it specifically to Mr. Thompson.
8 And Mr. Thompson's case is one of the strongest cases of
9 temporal relationship and challenge/rechallenge evidence
10 available.

11 Your Honor, Ms. Leskin raised a point that the
12 University of Alabama wouldn't let Dr. McGwin release the
13 records of his patients. There's a very good reason why he
14 didn't let the records out. The University of
15 Alabama-Birmingham, where these patients had come from, due
16 to HIPAA rules and other university policies, would not
17 allow him to release the information. We told Pfizer they
18 could subpoena the records. Try to contact UAB's counsel
19 and we were willing to cooperate with them in getting these
20 records and they haven't done so.

21 THE COURT: I'm going to tell you, counsel, if
22 we're going to operate courts of law, we're going to figure
23 a way out through that. Not just in this case.

24 MR. OVERHOLTZ: I agree. Getting through HIPAA is
25 big.

1 THE COURT: We got to get that problem fixed.

2 MR. OVERHOLTZ: I agree.

3 MR. BECNEL: I can give you a good example of how
4 it was fixed with Judge Pallin (phonetically spelled).

5 THE COURT: We'll talk about that later. I've got
6 a time limit on this guy.

7 MR. OVERHOLTZ: It should be noted that in
8 searching for the truth regarding the epidemiology and what
9 Dr. McGwin knew and didn't know in conducting his study,
10 that none of Pfizer's employees ever contacted Dr. McGwin
11 about his study at all. And Ms. Leskin attacked the
12 subgroup analysis that had been done, but one of the
13 documents that we cited to your Honor in our brief -- and
14 I'll try to re-point it out to your Honor, I don't have it
15 with me -- but they concluded Pfizer's own analysis of the
16 study is that he was bound to report the results that he saw
17 with men who had previous myocardial infarctions because it
18 was a very obvious sign and signal.

19 And, your Honor, we talked about the greater than
20 five times risk that Dr. McGwin reported regarding people
21 with myocardial infarcts and their risk of NAION when taking
22 Viagra. And this comes out of the Reference Manual on
23 Scientific Evidence. A relative risk of ten as seen with
24 smoking and lung cancer is so high that it is extremely
25 difficult to imagine any bias or confounding factor that

1 might account for it.

2 And while they may have criticisms as to what
3 Dr. McGwin compared those results to, those are criticisms.
4 And as this Court has stated over and over again, those go
5 to the weight of the evidence, not to the methodology
6 applied by the expert.

7 Your Honor, to conclude, you asked Mr. Hopper when
8 this was a -- don't our experts have to be doing more than a
9 shot in the dark. And it's kind of funny because for
10 Dr. Hayreh that's exactly what this is for a lot of these
11 patients. Is a shot in the dark. But it's not a shot in
12 the dark. It's not an ipse dixit conclusion. It's a
13 reasonable scientific conclusion based on years of
14 experience, years of practice, years of studying blood flow
15 properties, profusion properties.

16 And in the case of Dr. McGwin and Dr. Pomeranz and
17 Dr. Aruna in looking at plausible biological evidence stated
18 by the world's leading expert on NAION and ocular blood
19 flow, looking at the epidemiology reported by the Margo &
20 French Study, which was a large study related to a study of
21 veterans and their case reports, evidence such as the men in
22 India who took the sildenafil, the case reports of the men
23 who took Cialis or who took sildenafil had a visual adverse
24 event; took the product again, had another event and the
25 vision apparently became impaired, looking at all of that

1 evidence, looking at the evidence and concluding that Viagra
2 can cause NAION, those are experts applying the rigors of
3 intellectual analysis that they would apply in their field.
4 And that methodology is appropriate and based on sound
5 fundamental scientific methodology and they should be
6 allowed to testify to a jury.

7 THE COURT: Counsel, you were kind of summing up.

8 MR. OVERHOLTZ: I'm done, your Honor.

9 THE COURT: I want to bring you back to Dr. Aruna.

10 MR. OVERHOLTZ: Okay.

11 THE COURT: The concern that I have with
12 Dr. Aruna. Dr. Aruna is a pharmacologist and yet his
13 opinion is based in a fair amount on physical anatomy and to
14 the vascular structures. Those two things don't kind of fit
15 with me.

16 MR. OVERHOLTZ: And, your Honor, I think we can
17 probably look at the cases that have looked at the
18 introduction of pharmacologists around the country in
19 different pharmaceutical litigation and you see some courts
20 that let them in, gave them latitude to talk about the
21 pharmacology of the drug and how it applies to the
22 physiology of the body. Some courts have limited it and
23 said I'm just going to let you talk about the
24 pharmacological properties of the drug.

25 I think what the Court has to do in applying the

1 flexible approach to Daubert that the case law allows for is
2 look at what a reasonable pharmacologist does in their field
3 of expertise. And Dr. Aruna teaches pharmacology, teaches
4 the effects of these drugs to students at Xavier University.

5 And Dr. Aruna does have a knowledge and he relies
6 upon the expert reports and the medical literature that is
7 published by Dr. Hayreh and others on the feeds of ocular
8 blood flow and relies upon the epidemiology. And for him to
9 rely upon what Dr. Hayreh has reported, what Dr. Pomeranz
10 has reported about crowded disc and blood flow to the eye
11 and what Dr. Hayreh has reported about profusion, that's
12 what pharmacologists do in looking at causal relationship.
13 They don't just do it in a science lab experience by
14 swabbing products on tissue.

15 And I think that the methodology applied is a good
16 methodology based on sound reasonable grounds for a
17 pharmacologist. Certainly they question him, Are you a
18 medical doctor? They can cross-examine him. But I think
19 that goes to the weight of Dr. Aruna's testimony and not to
20 the admissibility.

21 THE COURT: All right. Thank you very much.

22 MR. OVERHOLTZ: Thank you, your Honor.

23 MS. LESKIN: Your Honor, we would ask for five
24 minutes or so to get ourselves together.

25 THE COURT: Sure. I'll do that, although I'm

1 going to encourage counsel that somehow or other in the
2 rebuttal phase that we have come up with now that we kind of
3 minimize the electronics so we don't have to take another
4 five-minute break. We're running a little tight.

5 (Recess taken from 11:42 to 11:50 a.m.)

6 MS. LESKIN: Your Honor, I'm going to attempt to
7 do this without my computer so bear with me.

8 Just a few points I want to address. Mr. Becnel
9 started talking about this folklore tale of how Viagra came
10 to be. And, in fact, what the testimony is is that during
11 the course of a clinical trial to treat angina, adverse
12 event reports of erection were reported to Pfizer.

13 Now, Pfizer did not take that adverse events
14 report and go out and start selling the drug to treat
15 erectile dysfunction. Instead they generated a hypothesis
16 and they conducted a study and those studies showed that the
17 drug was effective and that it was safe. So that just
18 underscores that the gold standard here is testing. Not
19 theory, not a case report, but testing.

20 Counsel spent a lot of time talking about the
21 expertise of Dr. Hayreh and Dr. Pomeranz, but that's a
22 separate inquiry from reliability. And the qualifications
23 of an expert do not immunize them from an assessment of the
24 reliability of their opinions. Daubert says the opinion can
25 be and has been tested, not we're thinking about testing it,

1 we're trying to test it, but has been tested.

2 Mr. Overholtz referred to the methodology behind
3 Dr. McGwin's study. We don't challenge the methodology. We
4 don't challenge the choice of conducting a case control
5 study. But the fact of the matter is that the study did not
6 prove anything. And so as it stands, as a proper
7 methodology, reliance on the -- of the failure to find is
8 the problem with the methodology here.

9 And all the experts testified that that study
10 failed to find a statistically significant increased result.
11 Mr. Overholtz claimed that it was a leap of science to go
12 from the blood flow studies that do exist to a finding that
13 Viagra somehow has an effect to increase blood flow in the
14 optic nerve head. But in fact it requires -- decrease, I
15 apologize. No, it increased. In fact, though, it requires
16 a five times greater leap of faith to conclude that every
17 study around that optic nerve finds it ain't decreasing or
18 no change; but yet that vessel, those vessels in the optic
19 nerve, somehow decrease blood flow.

20 Mr. Overholtz pointed to the lack of animal
21 studies because there's not an appropriate animal model.
22 Again, the lack of animal studies is a reason to exclude the
23 expert's opinion, not let it get a free pass and admit them.

24 Mr. Overholtz pointed the Court to two new
25 studies. I haven't seen them. I'm not a scientist. I'm

1 not going to purport to sit here and tell you what they do
2 or do not mean. But significantly Plaintiffs' experts have
3 not cited those reports, and they are not admissible without
4 an expert to rely on them. And so if Plaintiffs choose
5 to -- seek to rely on those studies, the proper procedure
6 would be for them to move to reopen the record, have their
7 experts submit supplemental reports and be reopened to
8 deposition, and then we can have a proper discussion of
9 those reports.

10 Mr. Overholtz did not play you a single piece of
11 their experts' testimony. We showed you video and
12 transcript of their own experts acknowledging the lack of
13 studies and the lack of data supporting their opinions. But
14 yet you did not see one piece of testimony from
15 Mr. Overholtz supporting their experts. Mr. Overholtz stood
16 up here and told you that the subgroup analysis was borne
17 out in the case reports and in these cases. No expert has
18 said that and those documents aren't even in the record.

19 To the contrary, Dr. Pomeranz wrote in his report
20 that a more compelling case could be made for those patients
21 with no cardiovascular risk factors. Mr. Overholtz made a
22 challenge to the Gorkin Study challenging the analysis of
23 one of these studies cited in that paper. Again, no expert
24 has conducted that analysis and no expert has made that --
25 has made that statement on the record.

1 Mr. Overholtz spent a lot of time talking about
2 Viagra's effect on blood pressure. No expert has given that
3 opinion and no expert has cited that information.

4 You asked Mr. Overholtz whether anyone has
5 suffered NAION after taking nitrates. Well, the fact of the
6 matter is, as Mr. Overholtz pointed you to, no one has done
7 that study. And he tried to explain it to you because
8 people don't take it at night. Well, this is what we talked
9 about at Dr. Hayreh's deposition. This is from
10 Dr. Hayreh -- Dr. Hayreh's deposition. And we're talking
11 about sleeping pills. And I asked him:

12 "Q. And sleeping pills I think we can agree are
13 taken at night. Are you aware of any studies that show a
14 higher rate of Ischemic Optic Neuropathy among patients
15 taking sleeping pills than among patients not taking
16 sleeping pills.

17 A. Nobody has done the work on that."

18 So then we talked about medications to treat blood
19 pressure and whether they cause an abnormal drop and he
20 identified some of them. So I asked him:

21 "Q. Are you aware of any study that shows an
22 increased rate of Optic Neuropathy among patients taking
23 beta blockers," which causes a drop in blood pressure, your
24 Honor, "as compared to patients not taking beta blockers?

25 A. Nobody has done that study.

1 Q. Are you aware of any study showing an
2 increased rate of Ischemic Optic Neuropathy among patients
3 taking ACE inhibitors as compared to patients not taking ACE
4 inhibitors?

5 A. As I said, nobody has done those tests.

6 Q. Are you aware of any studies showing an
7 increased rate of Ischemic Optic Neuropathy among patients
8 taking calcium channel blockers as compared to patients not
9 taking calcium channel blockers?

10 A. As I said, nobody done those studies."

11 And when we asked Dr. Aruna and Dr. Pomeranz
12 whether nitrates causes NAION, they both said not to my
13 knowledge.

14 You asked, your Honor, about the combination of
15 PDE-5 inhibitors and whether there was any basis to compare
16 them or contrast them. Well, every expert that was asked
17 the question testified that they were not aware of the
18 differences between Viagra and Cialis. This is from
19 Dr. Pomeranz's deposition. And in talking about the class
20 of drugs known as PDE-5 inhibitors I asked him:

21 "Q. Do you know the difference in chemical
22 composition between sildenafil, tadalafil and vardenafil?

23 A. Not the details of them, no.

24 Q. Do you know any of the differences in the
25 pharmacology of those drugs?

1 A. To the extent of how long they are supposed to
2 remain in the body, I believe Cialis is supposed to last for
3 a longer period of time, but beyond that, no.

4 Dr. Hayreh, talking about PDE-5 inhibitors, I
5 asked him:

6 "Q. Are you aware of what the difference is
7 between sildenafil, tadalafil and vardenafil?"

8 And he said: "No."

9 The only person who gave any testimony about the
10 differences are Pfizer's in-house doctor, Rachel Sobel. And
11 she was asked by Plaintiff:

12 "Q. Has there been a criticism of the particular
13 formulation from a safety point of view, of the Viagra
14 formulation as compared to Cialis and Levitra?"

15 And she said:

16 "A. Not that I am aware of.

17 Q. It's the same formulation? The three drugs?

18 A. No. Of course they are separate. There are
19 separate formulations. They are three different drugs with
20 three potential -- well, certainly with three different
21 pharmacokinetic profiles."

22 So your Honor was absolutely right in asking
23 whether the results can be legitimately combined for those
24 three drugs.

25 We spoke earlier about the temporality issue.

1 Dr. Hayreh -- and I failed to reference Dr. Hayreh's
2 testimony. I mentioned earlier that he acknowledged there
3 was no record at basis for his assumptions, and that could
4 be found at his deposition, pages 245 to 261 of his
5 deposition. It's a very lengthy clip and probably not worth
6 playing here.

7 We also spoke a lot about whether it can cause
8 NAION or whether it does cause NAION. And as we said, the
9 fundamental question is whether it is capable of causing
10 NAION at this point in time. And that conclusion has to be
11 through scientific evidence meeting the reliability
12 requirement of Daubert, not a theoretically possible theory
13 based on speculation. And that's not only Daubert, which I
14 read, but Dr. Hayreh's article. He has an article which is
15 Exhibit 8 to his deposition called Scientific Literature and
16 the Gospel Truth where he himself warns about hypothesis
17 without facts.

18 Glastetter recognizes that in analyzing the chain
19 of causation, the fundamental premises of that chain has to
20 be established. And Rosen, the quote I read earlier, that's
21 law led science, does not lead it.

22 So before we reach the question of whether
23 Plaintiffs can meet their burden of more likely than not, we
24 have to get to the question of reliability. And that's a
25 separate inquiry. And the determining factor is whether

1 there is a good grounds. There is evidence for those
2 opinions.

3 This Court has recognized that it's improper to
4 abdicate the gatekeeping responsibility. In McClain versus
5 Metabolife, the Eleventh Circuit said that a trial court
6 abuses its discretion by failing to act as a gatekeeper.
7 And in Joiner, the Supreme Court emphasized that although
8 the Court has a range of -- a range of testimony to find
9 admissible, the Court is in the gatekeeper role in screening
10 such evidence.

11 We're not talking about some day. We're talking
12 about what the evidence looks like now. We cannot ignore
13 epidemiology that exists. As the Tenth Circuit said in the
14 Norris case, that's Norris v Baxter, this is not a case
15 where there is no epidemiology. It is a case where the body
16 of epidemiology largely finds no association.

17 And so while we do not have to have epidemiology,
18 where there is a large body of contrary epidemiological
19 evidence, it is necessary to at least address it with
20 evidence that is based on medically reliable and
21 scientifically valid methodology. It is not reliable
22 methodology to rely on results that lack statistical
23 significance. It is not reliable methodology to rely simply
24 on case reports. It is not reliable methodology to deposit
25 a biological mechanism without any tests to confirm it. It

1 is not reliable methodology to refuse to read the clinical
2 data as Dr. Hayreh did, ignore the animal testing and to
3 ignore blood flow testing. And it's not reliable
4 methodology to conclude from studies that show no decrease
5 that there must, in fact, be a decrease. Without that
6 reliable basis, Plaintiffs' experts' opinions fail.

7 Unless you have any other questions, your Honor,
8 I'm going to sit down.

9 THE COURT: Okay. Thank you very much.

10 MS. LESKIN: Thank you.

11 MR. BECNEL: Judge, Mr. Overholtz is going to talk
12 to the Court now about the few things that we have.

13 MR. OVERHOLTZ: Your Honor, I'll try to be brief.

14 Your Honor, just to address a couple of points
15 that Ms. Leskin made, Plaintiffs' experts here do not rest
16 on their qualifications. Instead, they rest on the sound
17 fundamental scientific methodology employed in reaching
18 their conclusions from Dr. McGwin, Dr. Hayreh, Dr. Pomeranz
19 and Dr. Aruna.

20 Ms. Leskin brought up the point of the two new
21 studies that we brought up in our argument that have just
22 come out. Obviously our experts -- they may have
23 actually -- I think our experts are the ones that provided
24 us with the animal pig study just this past week, as well
25 as --

1 THE COURT: Well, counsel, let's face it. I
2 haven't seen that thing and it may mean nothing, it may be
3 very important. If it's in that latter category, it will
4 get here in its due time in its own way. We'll deal with it
5 then.

6 MR. OVERHOLTZ: Yes, your Honor.

7 I talked about Ms. Leskin brought up the leap of
8 faith that I argued that their blood flow studies really
9 required. And I think it's important to note that -- and
10 this came from Pfizer had a meeting, and I don't know if the
11 ELMO is up. Is it on right now?

12 This came from a -- this sildenafil retinal blood
13 flow brainstorming session that Pfizer had down in
14 Ft. Lauderdale April 30, 2006. Mitch Brigell, Alan Laites,
15 as well as other authors of blood flow studies, and they
16 were talking about this issue.

17 And this is a doctrine I read from earlier, your
18 Honor, which was the Pfizer response to the studies in
19 patient populations treated with sildenafil. And just to
20 show you that this addresses the inadequacies of the
21 available technology: "They would have no relevance to the
22 risk of NAION. They are insensitive to the change in flows.
23 Thus, color Dopplar is of no use in assessing NAION risk."

24 And there's another type of study that I responded
25 to but which is this dye-related test, just like doing an

1 angiogram of the eye. You insert dye in the eye and it does
2 have side effects and which is why it isn't done. This is
3 Pfizer's position that: "No existing technology can measure
4 the vasculature involved in NAION and therefore any study
5 performed in patients would not be indicative of the risk of
6 developing NAION."

7 I wanted to raise this. At the same meeting they
8 talked about some of the case reports, the case reports and
9 the medical literature. And they talked about the Pomeranz'
10 report but advised by Pfizer in their brainstorming session,
11 and this is their summary, "a well-documented case by
12 Dollinger and Lee presents a positive rechallenge with
13 tadalafil and provides the strongest evidence of an
14 association between PDE-5 inhibition and NAION."

15 And while, your Honor, we don't argue that case
16 reports alone would support analysis, but as the Eighth
17 Circuit has recognized in Bonner and this Court has cited,
18 the information contained within those case reports can
19 contain very relevant information. Some case reports lack
20 information.

21 But where you have case reports involving specific
22 information regarding temporal relationship like Pomeranz's
23 case reports did, where you have evidence of challenge and
24 dechallenge, those are very relevant to an expert in
25 considering all of the evidence. It's not just about the

1 single little blocks. It's about the entire building blocks
2 of evidence that these experts look at in their course in
3 forming their opinions.

4 Judge, they mention that some of the other drugs
5 of blood pressure that they questioned Dr. Hayreh about,
6 from sleeping pills to the other blood pressure drugs, it
7 should be noted that Defendants cite Glastetter, the
8 parallel case for the proposition that a mere generic
9 assumption that two drugs act alike carries little
10 scientific value. And that's the case here. Assuming that
11 all of these blood pressure drugs act the same in the body
12 and cause the same types of effects without evidence of that
13 just is not appropriate. But we're not here to talk about
14 other drugs. We're here to talk about Viagra and --

15 THE COURT: Counsel, that's a precise problem that
16 we have because you're saying a lot of stuff in front of me
17 that talks generically about erectile dysfunction drugs
18 without defining which drug is the applicable drug to this
19 particular study. And that becomes a very difficult
20 situation because, you know, one of these guys studied 14
21 people. He studies 14 people. If it turns out all 14 of
22 them are Cialis, we're going to have spent a fortune
23 preparing a case for trial that is going to be pretty short.

24 MR. OVERHOLTZ: Your Honor points out a potential
25 weakness in almost any of our expert's testimony if they

1 acknowledge that these studies were about other drugs.

2 These studies were about Viagra.

3 I think Dr. McGwin's testimony reveals that many
4 of these were involving taking Viagra because of the
5 similarities of the class and the pharmacological mechanism,
6 I think it was inherent in the nature of scientists studying
7 this in the field, not for purposes of litigation.

8 Obviously we would have had them only focus on Viagra but
9 for the purpose of science focused on the class.

10 But there are studies in the evidence that do only
11 address Viagra and those studies involve the case reports
12 reported by Dr. Pomeranz. The reports of challenge and
13 dechallenge involved sildenafil and Viagra, as well as the
14 studies that Dr. Hayreh relies upon in the studies and the
15 effects of Viagra and in lower blood pressure that
16 specifically only deal with the effects of that. They do
17 have different pharmacological mechanisms. Viagra's time of
18 action and its profile specifically says it begins to leave
19 the body within six hours. Therefore, if you take it at
20 night right before bed, if you don't have the event within
21 the next 12 to 24 hours, you begin to question whether or
22 not the event has a temporal relationship.

23 The evidence at least that Pfizer has presented to
24 the FDA is there's at least a two-day period of risk for
25 Viagra. That's the difference with Cialis and the other

1 drugs. There's a longer period of risk. If your Honor
2 reviews the evidence with the study for the patient who took
3 the other drugs, they are going to apply.

4 I would like to take us back for a minute to the
5 case law and what we have here is very similar to what this
6 Court has addressed in the US Xpress case. The US Xpress
7 versus Great Northern Insurance case involved the Volvo
8 trucks. The expert that the Defendants were attempting to
9 exclude had performed testing on a truck but his testing was
10 not conclusive. It couldn't reach an answer. And the Court
11 said that: "Beauchamp is qualified to testify concerning
12 the simple field test that he performed. Furthermore, the
13 Court will admit the deductions that Beauchamp made based on
14 the test. Great Northern's arguments concerning the
15 conclusiveness of the test and the failure to perform other,
16 more conclusive tests affect the weight of Beauchamp's
17 testimony, not its reliability." The fact that Dr. Hayreh
18 hasn't tested this exact scientific mechanism at the
19 cellular microvascular level because he can't doesn't mean
20 that he can't draw deductions based on his scientific
21 knowledge.

22 In the Hernandez case, your Honor rejected the
23 Defense's attempts to exclude an expert in a mobile home
24 case. It conducted tests of other types of cooking oils and
25 it appointed a scientific literature regarding those oils

1 and the Court stated that: "The Court must customize their
2 inquiry to fit the facts of the particular case. Although
3 the Defendant is free to challenge the accuracy of the fire
4 investigation reports, the substance underlying
5 Mr. Anderson's opinion, and ultimately the validity of
6 Mr. Anderson's opinion, the Court finds that Mr. Anderson's
7 testimony is sufficiently rooted in legitimate scientific
8 methods and procedures to satisfy the science of Daubert."

9 That's the case here. Their testimony is rooted
10 in legitimate scientific methods and that's the inquiry
11 under Daubert. Not whether or not they reach the same
12 conclusion that everyone in the world has reached or the
13 Pfizer's opinions have reached.

14 And I would point your Honor to Ms. Leskin's
15 citation to the Daubert opinion and the key for testing.
16 And if -- I don't have her cases up here but the first word
17 in that paragraph that she read was "ordinarily". And I
18 think that's very telling in this case. And it has to do
19 with the Court's need, as your Honor has recognized, to fit
20 the inquiry to the facts of the case.

21 In Solheim Farms your Honor excluded the experts
22 because in that case the experts had not -- there wasn't a
23 question about whether or not tests could be performed; that
24 there was an inability to do tests. In that case testing
25 was available for the expert to perform to prove his theory

1 of causation but yet he didn't do the test. He didn't take
2 the step of taking the test. He was a lazy expert, so to
3 speak. That's not the case here. This is testing that --

4 THE COURT: If I remember right it was just a
5 farmer down the road.

6 MR. OVERHOLTZ: This is not the ordinary
7 situation. This is a situation involving a scientist like
8 Dr. Hayreh making reasonable deductions from valid
9 scientific evidence.

10 And as I would like to finally point to your
11 Honor, Judge Davis in the Baycol decision in failing to
12 exclude Dr. Smith from testifying stated that the exact --
13 the fact that the exact mechanism of injury is not yet known
14 does not affect the admissibility of the expert's opinion.
15 Judge Davis specifically noted that science is constantly
16 evolving and the fact that a theory is new or in the process
17 of becoming generally accepted does not prevent admission in
18 this case, citing the Ruiz case from the First Circuit.
19 Because the expert's hypothesis was well-reasoned and based
20 on relevant scientific literature as well as his years of
21 experience in toxicology, the Court allowed the opinion of
22 Dr. Smith under Daubert.

23 That's the case here. These experts have opinions
24 that are well-reasoned. They are based on relevant
25 scientific literature and they are based on years of

1 experience studying this issue, not for purposes of
2 litigation but in their fields of expertise. The same can't
3 be said for Defendant's experts and that's why your Honor
4 should deny Defendant's motion to exclude Plaintiffs'
5 experts in this case.

6 That's it. Thank you very much.

7 THE COURT: Okay. Counsel, we thank you very
8 much. I thank all of you for your presentations.

9 Mr. Becnel, you're ordered to be on your way.

10 MR. BECNEL: I'm late.

11 THE COURT: And I think I'll get a decision to you
12 just as soon as we can. I think we're scheduled to be back
13 next month on motions on causation. Are they cross-motions,
14 I can't remember?

15 MS. LESKIN: I believe, your Honor, that the
16 schedule had provided for -- Plaintiffs had made some
17 representation that they were going to file summary judgment
18 motions. Those were never filed. So I don't think there's
19 anything on the calendar.

20 THE COURT: Oh.

21 MR. HOPPER: I think we'll get back to the Court
22 on that for sure, your Honor. But Ms. Leskin characterized
23 it correctly. And I think we don't actually have anything
24 available to argue on the date that I think was provided by
25 the Court under the schedule that the Court set.

1 THE COURT: Okay. I see. Okay. The reason I was
2 going to lead up to this is that I got a 12:30 commitment
3 that I got to get to. It's out of the building and I'm
4 going to be late. When are you guys going to be back in
5 town? At some point in time we need to get into the next
6 steps.

7 MR. BECNEL: Depends on Guidant and Medtronics.
8 We don't have the dates set right now but that might come
9 back.

10 MR. HOPPER: Your Honor, if the Court wants us to
11 appear, we'll be here -- it's that simple -- for a status
12 conference and the like.

13 THE COURT: I thought that there was another
14 pending motion in this. I was going to slough everything
15 off until then and thought that life would be fine. I think
16 the best thing we better do now is we'll get a decision out
17 then on this matter that's before the Court, and then we
18 will set up a status conference so we can work it out.

19 MR. OVERHOLTZ: Your Honor, is there any objection
20 to the document that we raised today in the motion as filing
21 supplemental evidence to our brief?

22 MS. LESKIN: We do object.

23 THE COURT: No. As matter of fact, it comes down
24 to this. All the stuff that you folks presented
25 electronically, I would appreciate even those things over

1 there, having little copies of them.

2 MS. LESKIN: You could have these, your Honor.
3 They make lovely wall paper.

4 THE COURT: Suzanne has me for breakfast when I
5 accept those things. She has to take care of them. But go
6 ahead and submit that stuff.

7 As to the studies that were referred to, go ahead
8 and submit them. I'm not going to tell you that they will
9 be considered because, quite frankly, what Ms. Leskin said
10 is a true statement and we all know that.

11 MR. OVERHOLTZ: Yes, sir.

12 THE COURT: But at the same token, we're dealing
13 at the bench level at this point and if there's something
14 that's going to be of benefit to the Court with it, you're
15 going to push it through the process. If it's something
16 that Ms. Leskin doesn't care, she doesn't care. And we'll
17 figure that out in due time. But we can't figure it out
18 now.

19 MR. BECNEL: What became particularly important is
20 the one by Alon Harris is, you know, we objected over and
21 over again to allowing the substitution.

22 THE COURT: Oh, yes.

23 MR. BECNEL: But he wasn't sick enough to keep
24 right.

25 THE COURT: I've heard that one before. I told

1 you I wasn't going to get excited then and I'm not going to
2 get excited now.

3 MR. BECNEL: All right.

4 MS. LESKIN: Thank you, your Honor.

5 MR. OVERHOLTZ: Thank you, your Honor.

6 MR. HOPPER: Thank you, your Honor.

7 (Court adjourned at 12:20 p.m.)

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11 I, Carla R. Bebault, certify that the foregoing is
12 a correct transcript from the record of proceedings in the
13 above-entitled matter.

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Certified by:

Carla R. Bebault, RPR, CSR

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