

[1] Herbert J. Nevyas, M.D.
[2] order.
[3] A: Oh, yes, it was out of order.
[4] Q: Take a moment to make sure they are all
[5] there, please.
[6] A: They are all here. Okay.
[7] Q: I think where I was is I was asking you the
[8] first time you developed an impression to explain
[9] what was wrong with Mr. Morgan that you wrote in the
[10] chart was on 9/24/98. That's where you put down
[11] odd.
[12] A: That's where I first had the idea that there
[13] was possibly something that was completely
[14] nonphysiologic, yeah. And before that I thought the
[15] problem was we just needed time for his cornea to
[16] smooth more. We were puzzled.
[17] Q: To be certain, I want to be sure that I
[18] understand that. So prior to 9/24/98 you considered
[19] that he needed time for the cornea to smooth and
[20] recover from the LASIK?
[21] MS. KRAMER: This is when he saw him?
[22] A: Or I was just plain puzzled. I didn't see
[23] him that often, but I was a little puzzled, but then
[24] again I wasn't primarily following him. I figured
[25] that time would tell.

[1] Herbert J. Nevyas, M.D.
[2] Q: Did you consider the possible diagnoses of
[3] malingering, hysteria, nuclear sclerosis or a
[4] physical problem that is retinal as being a
[5] complication of LASIK surgery?
[6] A: No.
[7] Q: Did you consider malingering, a physical
[8] problem that is retinal, hysteria or nuclear
[9] sclerosis as being an adverse event following LASIK
[10] surgery?
[11] MR. LAPAT: Objection.
[12] MS. KRAMER: Go ahead. You can answer.
[13] A: Absolutely not.
[14] Q: And why did you not consider it as an adverse
[15] event?
[16] MR. LAPAT: Objection.
[17] MS. KRAMER: You can answer.
[18] A: Because in my experience LASIK surgery does
[19] not cause nuclear sclerosis, does not cause retinal
[20] problems that were of this sort, although I thought
[21] something might be developing, but it does not cause
[22] hysteria or malingering, and he was getting
[23] gradually worse. He was pretty good right after.
[24] Usually a LASIK complication will show up
[25] immediately and then usually get better, not worse,

[1] Herbert J. Nevyas, M.D.
[2] so something was going on here and we were very
[3] puzzled, and that's why we very much encouraged
[4] other opinions.
[5] Q: When you say it shows up immediately, what
[6] time frame are you talking about?
[7] A: Within the first few days or months, first
[8] visit even. If you get a problem with the cornea,
[9] it is worse on the first day and then it gets
[10] better. It is common to have poor vision the first
[11] postoperative day and he had good vision the first
[12] postoperative day and then gradually got worse,
[13] 20/50, 20/70, 20/60 minus, 2/60, 20/60 plus. Well,
[14] that's not too bad. He stayed 20/60 for a good
[15] while and then 20/80. He came up to 20/50 here
[16] afterwards. He really didn't do that badly up until
[17] — we are talking through August of '98. Then he
[18] dropped to 20/70 by September of '98, 20/100 and
[19] 20/80 by April of '99. That was April of '99.
[20] 20/100, 20/80 July of '99. Something is going on
[21] obviously. It's not something with LASIK a year and
[22] a half afterwards that he is down to 20/100, 20/200,
[23] 2400. He is certainly getting worse for whatever
[24] reason, and it could have been any of these things.
[25] His responses are getting worse; let's put it that

[1] Herbert J. Nevyas, M.D.
[2] way.
[3] Q: Under your investigational protocol with the
[4] Food & Drug Administration, when was something
[5] considered a complication and when was something
[6] considered an adverse event? Let's do some
[7] complications first.
[8] A: We have a whole list of things which would be
[9] considered either complications or adverse events.
[10] Microkeratome problems where we have a bad flap, a
[11] hole in the flap, an irregular flap, irregular lines
[12] in the cornea from the cutting of the flap, an
[13] interface, diffuse lamellar keratopathy where you
[14] have a problem with the interface where you have
[15] inflammation in it, that's an adverse event. An
[16] infection is an adverse event. These are specific
[17] problems which we see which would be due to the
[18] LASIK, any of these things. It wouldn't have
[19] happened if he hadn't had LASIK. That's what I can
[20] think of. Decentration of the ablation,
[21] irregularity of the ablation, irregularity of the
[22] cornea, any of these things. These were what is
[23] considered. We have a list of things that we report
[24] to the FDA and check off. They do not include
[25] developing a cataract. They do not include