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IN THE COURT OF COMMON PLEAS

SUMMIT COUNTY, OHIO

- - -

MANOHAR LAL, etc.,)

Plaintiffs,)

vs.) Case No. CV92-04-1665

SUMMA HEALTH SYSTEM,)

et al.,)

Defendants.)

- - -

Deposition of HILLIARD M. LAZARUS, M.D., a
Witness herein, called by the Defendants for
cross-examination pursuant to the Rules of Civil
Procedure, taken before me, the undersigned,
William S. Bish, an RPR/CM and Notary Public in
and for the State of Ohio, at the office of
Hilliard Lazarus, M.D., University Hospital, 2074
Abington Road, Cleveland, Ohio, on Wednesday, the
16th day of December, 1992, at 2:20 o'clock p.m.

COMPUTERIZED TRANSCRIPTION BY
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APPEARANCES:

On Behalf of the Plaintiffs:

Messrs. Scanlon & Gearinger

By: Timothy F. Scanlon, Attorney at Law
1100 First National Tower
Akron, Ohio 44308

On Behalf of the Defendant St. Thomas
Hospital Medical Center:

Messrs. Roetzel & Andress

By: Thomas A. Treadon, Attorney at Law
Suite 520
220 Market Avenue, South
Canton, Ohio 44702-2106

On Behalf of the Defendants Dr. Mubashir
and Dr. Marquinez:

Messrs. Reminger & Reminger

By: Peter W. Marmaros, Attorney at Law
Suite 700
113 St. Clair Avenue
Cleveland, Ohio 44114

ALSO PRESENT:

Bashar L. Mubashir, M.D.
Manohar Lal, M.D.

- - -
I N D E X

<u>Exhibit No.</u>	<u>Page</u>	<u>/</u>	<u>Line</u>
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<u>Examination By:</u>	<u>Page</u>	<u>/</u>	<u>Line</u>
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1 HILLIARD M. LAZARUS, M.D.
2 of lawful age, a Witness herein, having been first
3 duly sworn, as hereinafter certified, deposed and
4 said as follows:

5 CROSS-EXAMINATION
6 (Defendant's Exhibit 1
7 was marked for identification.)

8 BY MR. TREADON:

9 Q. Doctor, my name is Tom Treadon, I
10 represent St. Thomas Medical Center in this
11 litigation. Have you met everyone here or --

12 A. Yes.

13 Q. Okay. And Mr. Marmaros, sitting to my
14 right, is an attorney representing Dr. Mubashir and
15 Dr. Marquinez, and I'm sure he'll have some
16 questions when I'm completed.

17 Would you state your full name and your
18 business address, please.

19 A. Hilliard Michael Lazarus, Department of
20 Medicine, University Hospitals, 2074 Abington Road,
21 Cleveland, Ohio 44106.

22 Q. And your occupation?

23 A. Physician.

24 Q. And, sir, you have provided us a copy of a
25 curriculum vitae which has been marked as

1 Defendant's Exhibit 1. Is this a current --

2 A. Yes, it is.

3 Q. -- CV? Just briefly, and I know it's
4 rather extensive, could you just tell me about your
5 medical training?

6 A. I was -- I went to medical school at the
7 University of Rochester. I did my internship, my
8 residency and my fellowship at the Case-Western
9 Reserve University. I've been on the faculty at
10 Case-Western Reserve University in medicine, in the
11 Department of Hematology and Oncology, since 1979.

12 Q. And you're Board certified in what
13 specialty, sir?

14 A. I'm Board certified in internal medicine,
15 hematology and also in medical oncology.

16 Q. Those are three separate --

17 A. Yes.

18 Q. -- Boards?

19 A. Three separate Boards, right.

20 Q. Okay. Are you aware there is a lawsuit
21 pending?

22 A. Yes, I am.

23 Q. Okay. And how did you become aware of
24 that?

25 A. I don't recall exactly whether I heard

1 from Dr. Mubashir or Dr. Lal or Mr. Scanlon, but I
2 believe I heard early, and I heard from a number of
3 sources that there was a potential for litigation
4 in this case.

5 Q. All right. Have you reviewed any material
6 prior to today relative to the care and treatment
7 provided to Sharad Lal at St. Thomas Medical
8 Center?

9 A. The only information that I have reviewed
10 is I have looked over in -- in general fashion,
11 when Mr. Scanlon contacted me, our hospital records
12 on Sharad that relate predominantly to his -- his
13 treatment and follow-up at University Hospitals.

14 I have not seen, per se, any specific
15 records that relate to his subsequent admission or
16 follow-up at St. Thomas, although I think I've seen
17 -- I think I had a note from Dr. Hazra, I have had
18 some follow-up over the phone with her when she
19 assumed his care. I believe -- I don't know if I
20 have it in here. I do believe I've seen some
21 follow-up describing the fact that what his disease
22 status was a while ago.

23 Q. All right. What do you have there in your
24 hand?

25 A. This is the medical record from the

1 University Hospitals of Cleveland, the Ireland
2 Cancer Center.

3 Q. Is that the entirety of the records you
4 have?

5 A. Yes, this is his chemotherapy admission,
6 his bone marrow transplant admission and his post
7 transplant follow-up to, I think -- I forget the
8 last entry, I think it was in September if I'm not
9 mistaken.

10 Q. September of this year?

11 A. No, I think September of -- of '91. I'll
12 tell you in a second. It's quite a lengthy
13 document, series of documents, as you can well
14 imagine. Here, this is it. My last note was
15 September 19th, 1991.

16 Q. Now, you've met with Mr. Scanlon
17 concerning this case?

18 A. Yes, briefly, just for him to point out to
19 me that -- that there was this litigation and just
20 in general what my -- I'm sorry, did I say
21 September 19th?

22 Q. You said September of '91, I believe.

23 A. Okay. Because I do have -- I don't know
24 where the letter is. I usually send a letter when
25 I see a patient. It may be in this file. I had --

1 the last note that I have here is October 3rd,
2 1991.

3 Q. Now back to your discussions with Mr.
4 Scanlon, what was that --

5 A. We -- pardon --

6 Q. What were you asked to --

7 A. I think Mr. Scanlon --

8 Q. -- what were you advised your
9 participation would be in this case?

10 A. I indicated to Mr. Scanlon that I was
11 concerned as a practicing physician that this would
12 represent a potential conflict and a potential --
13 how should I say this -- I'm not in the habit of
14 interacting, you know, of -- of --

15 Q. With lawyers?

16 A. Well, in malpractice. I mean, I try to
17 stay out of that sort of thing if possible; and
18 certainly Dr. Mubashir has referred us cases, and I
19 didn't want to be in an adversarial relationship
20 with him, and I made that very clear to Mr.
21 Scanlon, who informed me that my involvement in
22 this case would be one predominantly of what I had
23 thought about Sharad's care after diagnosis, and
24 our involvement in his care, as opposed to what
25 happened subsequent to that.

1 Q. So you've not been asked to render any
2 opinions concerning the care Sharad received while
3 at St. Thomas Medical Center?

4 A. That is correct.

5 Q. And you don't have any opinions I take it?

6 A. Oh, I do have opinions, but I -- I'm bas-
7 -- I don't have the -- the facts -- I did not
8 review the records from -- but I do have opinions
9 if I'm asked about what I understood about the
10 care, et cetera, but I didn't -- I'm basing this on
11 secondhand information.

12 Q. And my next question then is what is --
13 where did you get your understanding of what
14 happened at St. Thomas?

15 A. Well, Dr. Lal telephoned me, I guess,
16 shortly after Sharad was -- he was supposed to -- I
17 think Sharad was supposed to see me on a Thursday
18 or Friday, and he was admitted the day before, and
19 I believe they had called to tell me that he wasn't
20 keeping the appointment and some data surrounding
21 why he would not be keeping that appointment.

22 And subsequently they -- he has -- both
23 Mrs. Lal and Dr. Lal related various bits and
24 pieces of what had transpired to me, and then Dr.
25 Hazra has -- had talked with me on several

1 occasions, basically giving me information about
2 what had happened, and then subsequently Mr.
3 Scanlon has given me -- I guess you've given me the
4 smallest data.

5 Q. Okay.

6 MR. TREADON: Tim, can we take it from
7 all of that that it's not your intention to ask Dr.
8 Lazarus any questions at any time in this
9 litigation concerning the care that was provided at
10 St. Thomas?

11 MR. SCANLON: Yes. What I -- our
12 position hasn't changed from what I told you
13 originally. I told you that it was not our
14 intention to ask Dr. Lazarus any questions about
15 the care and treatment he received, but that if you
16 asked him he has some opinions, but I'm not going
17 to open that door.

18 MR. TREADON: Okay. And I'm not going
19 to open it either.

20 MR. SCANLON: I told him that what we
21 would want from him was his testimony, as Sharad's
22 doctor, concerning his diagnosis, his treatment and
23 his opinion as to the prognosis for that leukemia.

24 MR. TREADON: Fine.

25 MR. SCANLON: That is what we

1 discussed.

2 THE WITNESS: That is correct.

3 MR. TREADON: Do you want to ask him
4 something?

5 MR. MARMAROS: No, I'm here to listen
6 to what opinions he's going to be offering.

7 MR. TREADON: I thought you were going
8 to say something. I'll give you that opportunity.

9 MR. MARMAROS: No.

10 BY MR. TREADON:

11 Q. Doctor, I'm not going to ask you any
12 questions about the standard of care or the
13 treatment provided to Sharad during his stay at
14 St. Thomas Hospital Medical Center. Can you tell
15 me how you first became involved in his care?

16 A. Well, let me ask one more time.

17 Q. Sure.

18 A. I don't want to be in -- I don't want to
19 be in an unusual -- in an awkward position. And if
20 -- if this is the intent of any of you gentlemen,
21 that you want me to render an opinion, I will be
22 willing to do so but only if I'm provided with that
23 information, unless you want an opinion.

24 Q. In other words, the charts from the
25 hospital?

1 A. Yes. I think that that would be only
2 appropriate, that would only be fair.

3 Q. And I agree with you.

4 A. Okay.

5 Q. I agree with you. When did you first
6 become involved, and certainly you can refer to all
7 the charts that you have there in front of you --

8 A. Thank you.

9 Q. -- with Sharad's care? Am I pronouncing
10 that right, Sharad, or is it Shirad?

11 MR. SCANLON: How do you pronounce it?

12 DR. LAL: Sharad.

13 MR. TREADON: Sharad, all right.

14 THE WITNESS: Okay, all right. I
15 believe I saw Sharad for the first time on February
16 the 5th of 1991.

17 BY MR. TREADON:

18 Q. And how -- how did you become involved,
19 was this a consultation?

20 A. This is as a consultation, that's correct.

21 Q. From whom, from which physician?

22 A. From Dr. Mubashir, as well as Dr. Francis,
23 who is an infectious disease specialist involved in
24 his care.

25 Q. All right. Tell me about what you did.

1 A. Well, I evaluated Sharad as a potential
2 candidate for a bone marrow transplant procedure,
3 which is a particular treatment option that has
4 prospects of providing therapy with a curative
5 intent.

6 One of -- you didn't go through my
7 credentialing which is detailed in my -- in my CV,
8 but for a number of years I have run the transplant
9 program for the Case-Western Reserve University,
10 and this is one of our tertiary care areas of
11 expertise. And as the Director I evaluate many
12 such patients for that particular type of therapy.

13 Q. All right. And what was the result of
14 your evaluation?

15 A. I thought that he would be a very good --
16 really be an excellent candidate to undergo a bone
17 marrow transplant, and discussed that procedure in
18 specific detail with -- with his -- I believe his
19 mother was there as well, both his father and his
20 mother were all in the initial visit.

21 DR. LAL: Yes.

22 BY MR. TREADON:

23 Q. All right. And what -- what is the
24 criteria, if you could in a summary form, for your
25 determination that he was an excellent candidate?

1 A. Well, first of all he was -- he had acute
2 myeloid leukemia. Leukemia is broken down into two
3 major types, I'm talking about acute leukemia,
4 myeloid leukemia and lymphoid leukemia.

5 Myeloid leukemia patients who have no
6 active disease -- the words are complete remission
7 -- who undergo marrow transplantation at that time
8 have a very good chance of being cured of their
9 disease.

10 Now, he was in what we would term the
11 first complete remission, meaning that he was
12 diagnosed, he received chemotherapy at St. Thomas
13 Hospital and very promptly went into a complete
14 remission, meaning that all signs and symptoms
15 referable to the disease had disappeared. That's
16 obviously the first step in determining that his
17 disease is sensitive and that he could be a
18 candidate.

19 Now, he was otherwise an excellent
20 candidate in that he was a young man. He was 19
21 years of age, he had no other organ dysfunction or
22 other medical problems, for example a heart failure
23 or diabetes that couldn't be controlled or things
24 of that nature, so that in my opinion that this was
25 a very clear-cut case of a young man who could

1 tolerate this therapy with the prospects of being
2 cured of this otherwise lethal disease.

3 Q. And did you make that recommendation to
4 Dr. Mubashir?

5 A. I believe I sent Dr. Mubashir a long
6 letter which, as our records indicate, I did, I
7 sent Dr. Mubashir on February the 5th, 1991 a
8 two-page letter describing his course, my findings
9 and my recommendations for how to proceed. And the
10 prescription that I -- that I offered was followed
11 and subsequently he did undergo a bone marrow
12 transplant.

13 Q. Okay. And that was done here at the
14 University Hospitals?

15 A. Yes, in fact we provided interim
16 chemotherapy to further lower the leukemia cell
17 burden in his body. If you look at people who have
18 leukemia, when they are diagnosed they have overt
19 disease. After therapy the disease disappears, but
20 we know that the disease will come back very, very
21 quickly thereafter.

22 So we made the recommendation that he
23 get additional therapy, which he received, and then
24 he went on to a transplant. And both the
25 transplant and the interim chemotherapy, which is

1 referred to as consolidation chemotherapy, were
2 administered at University Hospitals.

3 Q. Could you describe for me what takes place
4 when you do a bone marrow transplant?

5 A. The concept of transplantation is that
6 larger doses of medication will get rid of more
7 disease than smaller doses, but in administering
8 larger doses of medication one damages normal
9 tissues. Chemotherapy is not specific for
10 malignant tissues and spares normal tissues, it's
11 shades of gray.

12 And while normal tissues can tolerate
13 chemotherapy significantly better than malignant
14 tissues, there is damage and -- and one of the
15 organs that is damaged most severely is the bone
16 marrow, which is the organ that manufactures blood.
17 So without regard for damage to the bone marrow, if
18 a person received very high doses of therapy, that
19 might eliminate disease but would result in the
20 permanent inability to manufacture blood.

21 By putting bone marrow back into a
22 patient's body after the completion of a high dose
23 therapy, that will enable the patient to get around
24 that marrow damage problem, that is, the bone
25 marrow will grow back and the ability to

1 manufacture blood will return.

2 There are many ways of providing those
3 cells, and they go by various names. If a person
4 receives bone marrow from another person, generally
5 a brother or a sister, who has the same bone marrow
6 type we refer to as a -- as an allogeneic bone
7 marrow transplant. As part of our initial
8 determination we determined that Sharad did not
9 have a bone marrow match among his brother -- among
10 his family members.

11 Another option is to use a person's own
12 bone marrow, which is referred to as an autologous
13 bone marrow transplant, and that is a little bit
14 different strategy. In that case the bone marrow
15 is not normal, that bone marrow theoretically could
16 still have leukemic cells contained therein, and
17 what is done is that bone marrow, after it's
18 removed from the patient, is treated with
19 chemotherapy just as the patient is treated with
20 chemotherapy, and that bone marrow is then given
21 back at a later time.

22 And that part, the giving back of bone
23 marrow, whether it's a brother's marrow or a
24 sister's marrow or your own marrow, is the
25 transplant. That -- that has little, if anything,

1 to do with -- well, that has little to do with the
2 -- with the elimination of the leukemia. What
3 eliminates the leukemia is chemotherapy, and high
4 dose.

5 Q. As I understand it you removed Sharad's
6 bone marrow?

7 A. That's correct. After he had recovered
8 from the chemotherapy that we had administered, I
9 believe six or eight weeks later -- I have to refer
10 to my notes to be specific -- his bone marrow -- we
11 attempted to collect his bone marrow and treat it
12 with chemicals and then freeze it. It turned out
13 that because of all of the treatment that he had
14 received that we came up with what we thought was
15 not sufficient bone marrow that would make us
16 comfortable, in other words that we didn't have the
17 wide margin of safety that we wanted, so we did two
18 bone marrow harvests on Sharad.

19 In that -- and in that period of time
20 we collected sufficient bone marrow that we were
21 very confident that we would not have problems with
22 that bone marrow growing back when we put it back
23 in the patient. Again I remind you that the reason
24 that this is of concern is that we are damaging the
25 marrow by treating it with chemicals in order to

1 eliminate any potentially remaining malignant
2 cells.

3 Q. Where do you harvest the bone marrow from,
4 what site?

5 A. Bone marrow is harvested from the back of
6 the hip bones, what we refer to medically as the
7 posterior iliac crests. That's done in an
8 operating room generally -- under general
9 anesthesia. It's a very straightforward procedure.

10 Q. All right. And then how long do you treat
11 the harvested bone marrow before it's implanted?

12 A. Well, the bone marrow, when it's obtained
13 in the fresh state, is treated in the laboratory
14 with chemicals, and that usually takes the better
15 part of a whole day to do. Then the marrow is very
16 carefully frozen.

17 If you've seen my laboratory next door,
18 all the hardware to do that and the technical
19 personnel are all under my supervision. That
20 marrow is frozen and could be stored for long
21 periods of time.

22 Then the patient is treated with very
23 high doses of chemotherapy. The bone marrow is
24 removed from these freezers where it's frozen about
25 300 degrees below zero Fahrenheit, and then that

1 bone marrow is infused, will recirculate through
2 the blood stream and then start to produce blood
3 cells.

4 Q. It is infused where, Doctor?

5 A. It's given through what's referred to as a
6 central venous catheter. What that is is a
7 semipermanent plastic intravenous device that's
8 inserted into the shoulder that goes into the great
9 vessels, and it's tunneled under the skin, and that
10 allows us not only to give the bone marrow back,
11 but it allows us very easy venous access for us to
12 give the antibiotics and the many transfusions and
13 the intravenous feedings that are necessary as part
14 of the transplantation process, in other words to
15 sustain the patient during the period when he or
16 she has experienced lots of damage from the
17 chemotherapy, the inability to eat and diarrhea,
18 sores of the mouth, low blood counts and the risk
19 of infection, et cetera, that -- that is how we
20 provide supportive care.

21 And those central venous catheters,
22 when they're maintained properly, can be -- can
23 remain in a patient for months at a time and will
24 -- and can be used on an outpatient basis to
25 continue to administer transfusions or other things

1 that may be necessary as a result of the transplant
2 procedure.

3 Q. How long does this procedure take, or how
4 long did it take in this case from start to finish?

5 A. You mean the hospitalization?

6 Q. No, the -- from the time of harvesting the
7 -- the bone marrow until the time it was then
8 replaced back in -- into his body?

9 A. It's usually about ten days. It's a day
10 to harvest the bone marrow and freeze it, and in
11 Sharad's case he received eight days' of
12 chemotherapy, and then there is a day of rest and
13 then the bone marrow is put back in. So it's
14 approximately ten days. I don't recall whether he
15 --

16 Q. All right.

17 A. -- immediately got started on chemotherapy
18 or whether it was another day of rest in there or
19 not. I don't recall.

20 Q. Okay. After the bone marrow is -- is
21 placed in his body then what happens in the course
22 of treatment?

23 A. Then, as I detailed to you, the supportive
24 care is critical because not only are we waiting
25 for the bone marrow cells to recover, to grow back,

1 which generally takes, even with very sophisticated
2 techniques, 30, 40 days to start to grow back, but
3 we have to wait for the damage to the other tissues
4 to wear off.

5 For example, there may be damage to the
6 liver, there may be damage to the lung, there may
7 be damage to the gastrointestinal tract as a result
8 of the high doses of therapy, and with time these
9 will -- these damaged organs will repair
10 themselves. And when they are -- when the blood
11 counts have returned to a sufficient degree, and
12 the organ damage has lessened, then those patients
13 are discharged and they're followed very closely in
14 the ambulatory setting.

15 Q. Okay. Were there any postoperative
16 reports -- complications in the case of Sharad?

17 A. He had a number of problems during the
18 transplant period, some of which reflected his
19 problems that he had had earlier. As I indicated
20 to you, Dr. Francis was concerned that he might
21 have had a -- an infection in his liver that would
22 be of some concern, and I believe we did a liver
23 biopsy to document that the liver bi- -- that the
24 liver was in good shape.

25 He -- he had low blood counts. Can I

1 read to you from my --

2 Q. Well, did he have anything --

3 A. -- note?

4 Q. -- that you would not expect as a result
5 of this procedure?

6 A. In other words, did he have any out of the
7 ordinary --

8 Q. Yes, sir.

9 A. -- problems?

10 No, he had the usual stormy course, and
11 that's why this is done at tertiary centers,
12 centers that have lots of experience in dealing
13 with these very sick people. But he did not
14 develop anything that we would have considered
15 unusual or out of the ordinary.

16 Q. How do you then determine the success of
17 the -- or failure of the bone marrow transplant
18 procedure? How do you monitor that and how do you
19 gauge your success?

20 A. Well, it's -- it's a procedure that one
21 has to define ultimately as a success being that
22 the leukemia does not recur at any time. That's
23 the -- that's our ultimate goal. This is designed
24 as a curative -- this is a therapy with curative
25 intent.

1 We perform analyses in the post
2 transplant period, really monitoring that, that the
3 toxicity of the therapy resolve. In fact, most of
4 -- the toxicities were resolving quite nicely
5 because, as I indicated in my last note to Dr.
6 Mubashir, that I thought that Sharad could probably
7 start back to college full-time in January of 1992,
8 and that we would monitor him with diagnostic bone
9 marrow examinations to ascertain whether the
10 leukemia was -- was detectable.

11 If the leukemia were to come back at
12 any time then that would reflect, you know, that
13 the transplant did not eradicate all the cells.
14 And my understanding is that he has, even to --
15 even till now has no evidence of -- of leukemia.

16 Q. Okay. You -- you noted before, or you
17 testified before that your last note was October
18 of '91. I presume, Doctor, that you continued to
19 follow Sharad after he left the hospital?

20 A. I may -- you may have misinterpreted what
21 I said. Let me clarify that. I said that I
22 followed Sharad before his -- you know, at the
23 beginning before his transplant, after his
24 chemotherapy, and then after the transplant, and he
25 had his bone marrow transplant, I think, on July

1 19th. Yes, he had his transplant on July 19th,
2 1991 and he went home, and I did see him in
3 follow-up in conjunction with Dr. Mubashir.

4 Our policy at our center has always
5 been to continue to maintain good contact with the
6 referring physician, and have the patient make --
7 maintain good contact with the referring physician,
8 so we generally follow patients jointly. We might
9 see them the first week and the third week of the
10 month, and then they might be seen by their local
11 doctor the second and fourth week, something along
12 those lines.

13 So we did continue to follow him after
14 discharge, in conjunction with Dr. Mubashir and his
15 group, but the last time that I believe I had
16 actually seen him -- again this is now three months
17 after -- the transplant was on October 3rd, 1991,
18 at least that's what my last note in the chart is.

19 Q. Okay. And what was done on the October,
20 1991 visit, what were your findings?

21 A. I indicated here that he was two and a
22 half months after the transplant, that we were
23 continuing to administer med- -- medication to
24 prevent the development of recurrence in his spinal
25 fluid, what we call intrathecal therapy, where

1 methotrexate medicine is put into the spinal fluid
2 as a preventive measure and that --

3 Q. For what purpose?

4 A. Again to prevent the development of
5 leukemia in an unusual location. And he received
6 that at that visit. I thought that -- that he was
7 doing quite well other than the fact that he had
8 the usual very slow recovery of -- of blood counts.
9 His blood counts were still on the low side, but
10 that was not totally unexpected given the
11 difficulty that we had in collecting bone marrow
12 from him.

13 Q. What is the significance of the
14 difficulty?

15 A. Well, as I pointed out to you, there are
16 some people who are more sensitive to chemotherapy
17 than other people, and you like to collect an
18 amount of bone marrow.

19 Q. Excuse me, Doctor, sensitivity as far as
20 curative or as far as the toxicity, or the adverse
21 --

22 A. Actually both --

23 Q. Oh, all right.

24 A. -- okay? His disease was sensitive to
25 chemotherapy, as evidenced by the fact that he went

1 into remission quite promptly.

2 We can digress for a minute and
3 describe the fact that there are types of leukemia
4 wherein the disease does not go into remission --
5 does not go into remission promptly, requiring
6 multiple courses or maybe perhaps more intensive
7 courses, so his disease itself was sensitive.

8 Similarly, his bone marrow was
9 sensitive to the toxicity of the chemotherapy in
10 the sense that it required us two separate bone
11 marrow harvest procedures to collect what we
12 believed to be a safe dose of bone marrow to use.
13 We did not do the bone marrow transplant after the
14 first harvest because we didn't think we had enough
15 cells, and we did a subsequent harvest, so we did
16 two.

17 And so the fact that his blood counts
18 when I saw him on October the 3rd, 1991 were still
19 low was consistent with the fact that his blood
20 counts reflected, you know, the toxicity from the
21 treatment, and it was going to be a while before
22 his blood counts came back up.

23 In point of fact we have a very lengthy
24 experience, as do others, and some people it takes
25 six, nine months. Some people linger until they

1 really get an adequate amount of blood counts.

2 This is a very intensive treatment.

3 Q. Now, you indicated that you use diagnostic
4 bone marrow biopsy, is that what you said, to
5 determine if the leukemia has returned?

6 A. That's the -- the only tried and true way
7 we have of assessing whether there is remaining
8 disease in any patient, we do -- this is an
9 outpatient ambulatory procedure.

10 Q. Was that done in October of '91?

11 A. If you'll permit me, I don't believe that
12 I did a bone marrow at that time. I think he had
13 -- I believe we had done one, I just have to refer
14 to my notes here. Let's see. The last one I have
15 that I did was on September 19th, 1991, which
16 showed no evidence of leukemia.

17 Q. What's that procedure called, a diagnostic
18 --

19 A. This is called a diagnostic bone marrow
20 aspirant biopsy. So in my -- in his visit on -- on
21 September 19th, 1991 I performed that exam, and
22 that was -- that showed no evidence of leukemia.

23 Q. From where do you aspirate the bone
24 marrow?

25 A. Again, from the back of the hip bones.

1 Q. And how often are the bone marrow biopsies
2 typically done after the transplant procedure?

3 A. Well, it depends on the -- on the disease
4 and depends on the type of treatment. In his
5 situation probably every two or three months would
6 have been the usual way that we would follow him.

7 Q. Was that done, to your knowledge --

8 A. Um-m --

9 Q. -- "that" meaning the diagnostic?

10 A. -- I know that he had had a couple of bone
11 marrows subsequently, according to Dr. Hazra.
12 Whether they did them religiously every two or
13 three months I don't recall, because of his
14 condition being what it was.

15 Q. Would that be the most definitive way to
16 determine if there had been a recurrence of the
17 leukemia?

18 A. They -- that's a way that gives you lead
19 time. In other words, if someone has recurrent
20 leukemia it has to start somewhere, and it starts
21 in the bone marrow. If you do not do a bone marrow
22 examination and you just ignore it, within a month,
23 or certainly within two months, the blood counts
24 would begin to reflect the leukemia, the blood
25 counts would -- would be essentially back where you

1 started, either you'd have circulating leukemia
2 cells that would be easy to find or the blood
3 counts would -- well, I mean, you probably would
4 have circulating leukemia cells.

5 Q. I guess you just lost me with that.

6 A. All right, I'll come back to that. If you
7 choose not to do bone marrow examination, the bone
8 marrow is where the leukemia lives. If and when
9 the leukemia starts up again it will return and
10 grow in the bone marrow.

11 Q. All right.

12 A. It grows in the bone marrow and grows in
13 the bone marrow and grows in the bone marrow, and
14 because the bone marrow has a blood supply, with
15 time the leukemia cells in the bone marrow leave
16 the bone marrow through the blood and circulate in
17 the blood stream. So if someone has leukemia and
18 you do not do a bone marrow exam within a month, or
19 at the latest probably two months, you could detect
20 a leukemia activity by just doing a blood test.

21 Q. All right.

22 A. We do this bone marrow examination for a
23 variety of reasons. For one thing it gives us some
24 lead time. In other words, we would know a month
25 or two before it got really out of control, we

1 would be able to detect it in its more incipient
2 stages of recurrence. Did that clarify?

3 Q. Yes, it does.

4 A. Okay.

5 Q. The last one that you were involved in,
6 the biopsy, was in September of '91. Did you get
7 reports from --

8 A. Yes.

9 Q. -- either Dr. Hazra or Dr. Mubashir --

10 A. Oh --

11 Q. -- with regard to subsequent biopsies? In
12 other words, did you continue to follow that aspect
13 of this patient's care?

14 A. I don't believe -- I could be wrong. I
15 did not look through the chart with that intent. I
16 do not believe I actually saw a report from Dr.
17 Hazra, unless it's misfiled, that said his -- his
18 leukemia is not active. Dr. Hazra did tell me on
19 -- over the telephone, you know, that his -- that
20 she had done a bone marrow, I believe, and there
21 was still no evidence of leukemia.

22 Q. Do you remember -- do you recall when that
23 phone conversation took place?

24 A. No, I'm sorry, I don't recall exactly.
25 But it was a while later, I --

1 Q. It was sometime after November of 1991?

2 A. Yes, yes.

3 Q. All right.

4 A. That's correct.

5 Q. All right.

6 A. And I don't have a copy of that record.

7 In my chart we try to get the referring physicians
8 to send us data. Sometimes that's easier than
9 others. We always try to provide a detailed letter
10 when we evaluate a patient, on all visits.

11 Q. I've not gone through your chart in
12 detail, Doctor, but what is the last activity as
13 far as University Hospital is concerned or your
14 involvement in Sharad's care?

15 A. I think again the October 3rd, 1991 is the
16 last clinical note that I have on his care at this
17 institution.

18 Q. All right. Do you have an opinion today
19 as to Sharad's prognosis?

20 A. Well, I can tell you that he has not
21 demonstrated evidence of relapse as far as I can
22 tell from what I've been told by Dr. Hazra. He is
23 -- his transplant was in July of 1991, so he has
24 essentially a year and a half since undergoing his
25 transplant, and if you review the data that we have

1 published, and others published in this area, the
2 likelihood of relapsing after a year in -- in
3 remission after transplant is vanishingly small.
4 So my opinion is that I think beyond a shadow of a
5 doubt -- I mean, it's beyond medical -- let me
6 rephrase that, whatever the language is, beyond
7 medical --

8 Q. You use the language you want to use,
9 Doctor.

10 A. I don't want -- there is a possibility
11 that lightning can strike this window.

12 Q. Well --

13 A. But I'm saying that it is extremely rare
14 that people will relapse after this period of time
15 having undergone a bone marrow transplant, such
16 that I would say I would -- I would feel reasonably
17 confident in saying that he is cured of his
18 leukemia at this point.

19 Q. Define cure for me.

20 A. Cure meaning that -- that the leukemia
21 will not recur in his lifetime, and hopefully under
22 normal circumstances we would have liked to have
23 seen him live another 50 or 60 years. I don't mean
24 to say that I can guarantee you --

25 Q. I understand.

1 A. I want to rephrase that. I don't mean to
2 say I can guarantee to you the disease will never
3 come back. I think the probability of his disease
4 recurring at this point is vanishingly small. It's
5 very small given the numbers, in other words, when
6 relapses may occur after this treatment.

7 Q. Assuming a normal life expectancy, you're
8 sating then that at least as far as the leukemia is
9 concerned you would not anticipate, or you think
10 the chances would be very, very small that it would
11 recur?

12 A. Yes, that's what I meant to say, correct.

13 Q. All right. You said it's rare that
14 people, after a bone marrow transplant, will
15 relapse after this period of time. I assume you're
16 referring to the year and a half?

17 A. Year and a half, that's correct.

18 Q. Now my next question you've partially
19 answered. Do you have any statistical data to --
20 well, let me ask it this way. What is the basis of
21 your opinion?

22 A. The basis of my opinion is that there have
23 been large numbers of patients treated in this
24 fashion in remission, that is, people that have
25 leukemia who go into remission, who get a bone

1 marrow transplant, that receive the type of
2 treatment that we administered.

3 And I know these data because my -- as
4 my -- my professional interest is in marrow
5 transplantation I am active in publishing, active
6 in participating in trials, and am a member of
7 several of the national and in fact international
8 boards that interact and present data. And the
9 likelihood of relapsing, you know, for any
10 treatment in leukemia is -- is something that's
11 published, and this particular regimen has been
12 very effective.

13 In fact again, our own personal
14 experience along with that published in the
15 literature would corroborate the statement that I
16 made that it is quite uncommon for people to have
17 late relapses after a bone marrow transplant using
18 this approach.

19 Q. How long has bone marrow transplant been a
20 procedure that's been used in the treatment of
21 leukemia?

22 A. The earliest studies were done in the late
23 1960's, and systemically I guess from the early
24 1970s on larger and larger numbers of patients have
25 undergone transplantation for leukemia, so that I

1 would say as a clinical tool this has been in
2 practice at large centers routinely for more than
3 20 years.

4 Q. Do you have any specific studies you can
5 refer us to that we could look at to -- that again
6 support your opinion that there is an infinitesimal
7 -- I can't recall the exact word you used -- very
8 small chance --

9 A. Very small.

10 Q. -- of a relapse?

11 A. Yes, I can provide you with --

12 Q. Do any come to mind?

13 A. Well, we published a study in Leukemia
14 reviewing the ECOG experience. ECOG is the Eastern
15 Cooperative Oncology Group, which is a large
16 consortium of prestigious medical centers that
17 interact to do trials, clinical trials in oncology
18 patients that include Johns Hopkins University,
19 Mayo Clinic, University of Pennsylvania, Albert
20 Einstein, a lot of prestigious centers, Stanford.

21 And our trial, which was essentially
22 what Sharad -- Sharad was treated, in fact very
23 similar, showed that -- that approximately -- that
24 the long-term disease re survival was quite
25 substantial. I can provide that to you. That was

1 published in Leukemia of this year.

2 There have been a number of studies
3 published in the European literature looking at
4 thousands of patients in the European transplant
5 consortiums -- I'll get it in a second -- there
6 have been studies in this country from Johns
7 Hopkins. There are lots and lots of trials that --
8 where this has been looked at. I mean, if you gave
9 me time I could provide you with easily a half a
10 dozen of those references.

11 Q. If you wouldn't mind doing that I would
12 like to see those, at your convenience.

13 A. Do you want me to do that now or at my
14 convenience?

15 Q. No, at your convenience.

16 A. All right.

17 MR. SCANLON: I'll write him a letter
18 reminding him for a list of references, and I'll
19 pass it on to you.

20 BY MR. TREADON:

21 Q. And maybe what you consider some of the
22 leading sources, and yours included, of course.

23 A. Are we talking about the specific type of
24 treatment that Sharad received --

25 Q. Yes.

1 A. -- or just leukemia and transplantation in
2 general?

3 Q. If you could make it more specific to his
4 case.

5 A. I will provide you with whatever you want.
6 I will provide you with a half a dozen or more
7 articles describing the fact that relapse late in a
8 transplant is quite uncommon after you're out a
9 ways. I'm not saying in the early period. When
10 you're out a year and a half, that's a pretty
11 significant event.

12 Q. Okay. Yes, if you could do that, and Mr.
13 Scanlon suggested --

14 A. Mr. Scanlon will remind me.

15 Q. Yes, he will. And I'll remind him if he
16 doesn't remember.

17 A. Okay.

18 Q. Are you familiar with Sharad's current
19 medical status aside from the leukemia?

20 A. By secondhand I'm familiar.

21 Q. Okay. You've not seen any of those
22 records?

23 A. I've not seen any of that information.

24 Q. And you've -- strike that.

25 Absent the events that occurred at

1 St. Thomas Medical Center in November of 1991, what
2 would you anticipate Sharad's course of treatment
3 would be, or follow-up with regard to the leukemia?

4 A. In other words, if -- if this --

5 Q. After, from November on?

6 A. -- if they had gone on to returning?

7 Q. Yes.

8 A. In my last letter, if I can tell you what

9 -- I --

10 Q. Certainly.

11 A. -- can tell you what I thought was going
12 on. I wrote --

13 MR. MARMAROS: September 5th.

14 THE WITNESS: Let's see. I think -- I
15 think I said that I anticipated that he would start
16 school in January of 1992. And what did I say?
17 Let me try to find the letter.

18 That would have been my -- my guess is
19 that he would have returned to school and hopefully
20 would have gotten on with his life. He still would
21 have needed to have close medical follow-up for --

22 Q. That's what I'm asking.

23 A. -- blood counting, bone marrow
24 examinations and the like.

25 Q. How --

1 A. We talked about that at length on several
2 of the visits, about --

3 Q. What would be the frequency of those?

4 A. -- probably, again, for the first two
5 years every -- every two or three months a marrow
6 examination, blood counting, that -- that sort of
7 thing.

8 Q. I note in your -- do you have your
9 September 2 or, excuse me, September 5, 1991 letter
10 there?

11 A. September 5?

12 Q. Directed to Dr. Mubashir.

13 A. September 5? I have September 19.
14 September 5, okay, okay.

15 Q. Well, apparently there is a --

16 MR. TREADON: Excuse us for a moment.

17 (Short recess had.)

18 BY MR. TREADON:

19 Q. In your September 5 correspondence I note
20 in the last full paragraph on the first page you
21 indicate, and I quote, "As you know Sharad also had
22 high risk for central" --

23 A. "Sanctuary site central nervous system
24 relapse."

25 Q. What -- did you mean to say also at high

1 risk or had high risk?

2 A. No, exactly what I said I meant. And I
3 described this to you earlier, that we had
4 administered -- because this particular kind of
5 leukemia, when it comes back, it can come back in
6 the spinal fluid. And as a means of prevent- --
7 and it might not come back elsewhere. As a means
8 of preventing that we administered chemotherapy
9 after the transplant, and in fact one of the
10 decisions as to how to treat him was to administer
11 chemotherapy at this institution prior to the
12 admission prior to the transplant with medication
13 that would penetrate the spinal fluid, high rate
14 cytosine arabinoside.

15 As part of our plan this is what we had
16 done, the high rate cytosine arabinoside and later
17 after the transplant methotrexate, which as a
18 matter of fact I gave him on a couple of occasions.
19 We did not demonstrate, by the way, that he ever
20 had spinal fluid involvement, and as evidenced by
21 clear spinal fluids all along.

22 Q. Is that spinal fluid involvement at a
23 later time, would that be part of the -- of your
24 opinion relative to reoccurrence? In other words,
25 could it reoccur in the central nervous system as

1 opposed to in the bones?

2 A. Oh, yes, certainly.

3 Q. Okay. Now, as I understand it the data
4 you have relates to about 20 years of experience
5 with bone marrow transplant, is that fair?

6 A. Well, the data that I've quoted to you are
7 the world's experience in bone marrow
8 transplantation where -- where beginning in about
9 1970 the patients with leukemia were systemically
10 treated. And as the supportive care improved, and
11 our understanding of treatments improved, new
12 agents, et cetera, we got better and better and
13 better such that in the late 60's, early 70's when
14 we were -- and I wasn't doing this till the
15 mid-70's -- people who had advanced end stage
16 disease were being treated, and some of whom were
17 being cured that this therapy got moved earlier and
18 earlier and earlier into the disease -- into the
19 course of the illness.

20 Q. Have these studies been able to follow
21 patients for 20 year periods, is that what you're
22 --

23 A. Well, some of the earlier studies clearly
24 have -- have -- some of the very early studies have
25 been followed, have patients that have been

1 followed for 20 years. The more recent studies --

2 Q. Obviously don't?

3 A. -- of course not. But -- but I like to --
4 in fact, if you permit me, I give a lot of
5 lectures, I can show you a slide --

6 Q. Sure.

7 A. -- of a patient --

8 Q. I'd love to see it.

9 A. -- who, you know, of what we sort of
10 expect. Here it is. I can show you some of --
11 again historically this is important to point out
12 of what things look like.

13 This is a slide that I made that I need
14 to update, it's an old slide, and it shows -- it's
15 from 1983. It shows the treatment of these people
16 who had really bad disease that was active,
17 refractory end stage, who were alive now. Once
18 they got -- most of these patients -- now, this is
19 from 1983.

20 All of these patients are still in
21 remission now, nine years later. The last one is
22 eight years. So almost all of these patients are
23 out 20 years if you can look at that slide, and
24 that's from -- that's not -- those are not my data,
25 those are data from the Fred Hutchinson Cancer

1 Center in Seattle. But from 1983, every one of
2 those patients are still alive.

3 Again, starting -- again, those --
4 those patients started to be entered in 1970. I
5 apologize I don't have a projector to show you.

6 Q. That's all right, I didn't anticipate that
7 you would.

8 MR. TREADON: Doctor, that's all the
9 questions I have.

10 MR. MARMAROS: I have a few, if I
11 could.

12 - - -

13 BY MR. MARMAROS:

14 Q. Doctor, from going -- from going through
15 your records the last letter I see that you
16 authored was the one we talked about, I believe, on
17 September 19th, is that correct, or --

18 A. Yeah. It's unclear to me why I didn't
19 write a letter, or why I didn't have a letter in
20 the file from October 3rd, but that's -- that's --
21 that's correct. The letter is the one I -- at
22 least this chart is September 19.

23 Q. Let me, if that's okay --

24 A. As far as I can tell that's correct.

25 Q. Fine, okay. Let me start with -- and I'm

1 going to be a little more basic, and maybe that's
2 because I need a little more basic. But let me
3 start with your letters and see if I can understand
4 a couple things.

5 On February 5 of '91, your letter, you
6 talk about -- and we know that Sharad ultimately
7 had an autologous bone marrow, correct?

8 A. Correct.

9 Q. All right. Did someone such as that, who
10 has to have an autologous bone marrow, do they
11 statistically or through your studies have a worse
12 prognosis?

13 A. That -- that -- no. As it stands right
14 now it is not at all clear that receiving -- this
15 is what I defined for you earlier. An allogeneic
16 transplant from a brother or a sister is preferable
17 to an autologous transplant. Those kind of studies
18 have not been done, they can't be done.

19 Q. Why is it -- go ahead. Why is it that
20 always the first course of action is to see if
21 there is a suitable donor instead of -- why don't
22 you always do it autologous?

23 A. Well, that's a very complicated question
24 to answer. I guess historically because allogeneic
25 bone marrow transplant has been performed for a

1 longer period of time, and because it's -- I don't
2 know -- maybe more scientifically appealing for
3 some to do that. That's the general strategy.

4 Most studies -- and I am involved in
5 one of the -- I was involved in the writing of the
6 national study. There is a -- the United States
7 has a big trial that's -- that's testing that exact
8 concept, it is comparing allogeneic bone marrow
9 transplants to autologous bone marrow transplants
10 or other forms of therapy; and by -- I guess by
11 tradition is a little strong for 20 years, but just
12 by the practice that's how it's generally
13 approached, that a patient under the age of
14 whatever who has a brother or a sister that is a
15 match is generally referred for an allogeneic bone
16 marrow transplant.

17 That is not always the case, number
18 one; and number two, there are individuals in whom
19 have been reported -- and we have had our own
20 experience -- who have gotten a bone marrow
21 transplant from a brother or sister and have
22 relapsed, and gotten bone marrow from themselves
23 that have gone into remission and remained in
24 remission longer than the first transplant. So
25 they are not mutually exclusive, they are merely

1 complimentary.

2 Q. So you're not aware of any studies as we
3 speak that talk about the lower instance of relapse
4 when receiving a bone marrow transplant from a
5 brother or sister as opposed to autologous?

6 A. No, I didn't say that, you're absolutely
7 correct. Let me rephrase that.

8 Q. Okay.

9 A. These are -- there are more problems with
10 doing allogeneic bone marrow transplants. There is
11 the problem of what's called graft versus host
12 disease where the donor bone marrow may attack the
13 patient and may result in his or her death, and
14 that's a much -- the people -- the early deaths
15 from allogeneic bone marrow transplantation are
16 much higher than with autologous bone marrow
17 transplantation. So that's problem number one.

18 So if we put things on a ledger, and we
19 say what are the advantages and disadvantages of
20 both of these -- and this gets complicated -- an
21 allogeneic bone marrow transplantation has the
22 disadvantage of having graft versus host disease.
23 You don't get that with autologous bone marrow
24 transplantation.

25 So there is not going to be a problem

1 of either the bone marrow not growing, which is
2 what we call failure to ingraft, which can happen
3 with a brother or sister transplant, or the problem
4 of graft versus host disease where the bone marrow
5 may -- may severely damage or even kill the
6 patient, you don't see that on the autologous.

7 On the other hand, the allogeneic bone
8 marrow the donor is a totally normal person, so it
9 is a normal bone marrow; and the autologous setting
10 the bone marrow is not normal. As I told you, it's
11 damaged bone marrow to begin with, and we damage it
12 further by giving -- by giving chemicals, so the
13 blood counts come back slower.

14 The other advantage -- the other
15 disadvantage is that while there is graft versus
16 host disease there is also what we call graft
17 versus leukemia, meaning the normal bone marrow
18 circulating in a patient, if it finds -- and I'm
19 oversimplifying for purposes of illustration -- if
20 it finds malignant cells still in the patient it
21 may kill those cells, so that the people who get an
22 allogeneic bone marrow transplant have a much lower
23 risk of relapse --

24 Q. That's what I'm --

25 A. -- than an autologous, but they have a

1 much higher chance of dying of a complication, of
2 an infection, because you have to use more
3 immunosuppression for graft versus host disease
4 than autologous, so when you start balancing things
5 the advantages and disadvantages are such that it
6 appears that they are similar in terms of overall
7 -- overall outcome.

8 I cannot tell you that one is
9 preferable to the other. I mean, people will argue
10 well, it's a little better; no, it's a little
11 worse. You can get the people -- but most people
12 you can get to agree, based on recently published
13 data, they're comparable, and it depends whether
14 you have a donor or not.

15 Q. Well, all things being equal though, if
16 you have your choice as the treating physician,
17 because of the increased risk of relapse, aren't
18 you going to opt for the identical or -- the
19 identical bone marrow, to get it from a brother or
20 sister, aren't you going to opt for that route?

21 A. Well, let me -- first of all no one has
22 those data. I can tell you what the best situation
23 we used to state was to have an identical twin. If
24 you had an identical twin you have no graft versus
25 host disease and you have normal marrow to put back

1 in. And in point of fact the relapse rates are
2 highest with an identical twin, they are higher
3 than with an autologous bone marrow transplant, so
4 that there is something about --

5 Q. Okay.

6 A. -- getting autologous bone marrow also
7 that is likely to result in a lower relapse rate,
8 so that in fact is not accurate.

9 Q. Okay. The relapse rates that -- do you
10 have literature with which you were going to
11 provide Mr. Treadon --

12 A. Yes, I can provide you with that
13 information.

14 Q. -- which relay higher incidence of relapse
15 rates but lower --

16 A. Lower incidence of death due to
17 complications.

18 Q. Understood.

19 A. Yes.

20 Q. Okay. In your March 22nd, 1991
21 transmittal, and I'm sorry, it's a transmittal from
22 Dr. Gersden --

23 A. Say again, what?

24 Q. There is a transmittal of March 22nd, 1991
25 from Dr. Gersden.

1 A. Okay.

2 Q. Dr. Gersden indicates in the first full
3 paragraph, it says, "Of note is the presence of a
4 chromosomal translocation."

5 A. Uh-huh.

6 Q. He says T-911. What -- how does that
7 impact upon prognosis, if at all? Maybe you can
8 just explain to me what all that means.

9 A. Okay. Let me just put this in two broad
10 categories.

11 Q. Okay.

12 A. When a person walks in the door off the
13 street with leukemia -- and again I like to be on
14 record to say that statistics are helpful if you
15 happen to be a hundred people and you're in -- you
16 know, so many are in one group and so many are in
17 the other, but you can't be in both groups, you
18 can't be a little bit pregnant. When we give
19 people statistics it's useful, but it doesn't say
20 which group you're going to be in.

21 When someone walks in the door we like
22 to have an idea of, one, the natural history of the
23 disease. Are there things we should be doing now
24 so that when we get down the road we don't say
25 "Gee, wouldn't it be nice, we should have thought

1 of this, you should have done that"; and second of
2 all to get an idea of is someone at a high risk, a
3 good risk, a low risk, should we be starting to
4 gauge our therapy to do more intensive, less
5 intensive.

6 In other words, it's just as bad to
7 treat with a howitzer when you can use a fly
8 swatter and vice versa. When they walk in the door
9 we do a whole bunch of things, determine what their
10 disease is, in this case leukemia, determine what
11 sub-type of leukemia in broad categories, in this
12 case myeloid leukemia rather than lymphoid.

13 And then to go further that there are
14 seven or eight different kinds of myeloid
15 leukemias, okay? It is not altogether clear that
16 any one of them is any worse than any of the other
17 ones, although there are unusual associations, one
18 of which is the fact that Sharad had the so-called
19 Fab M-5 myel- -- myeloid leukemia, which means that
20 his particular kind of leukemia is a myositic
21 leukemia, it's usually fingerprinted, we can look
22 right into the cell and blueprint the cell with the
23 chromosomes.

24 He has a translocation 911. In other
25 words, those two go hand in hand, one is the

1 phenotype, one is the genotype. In other words,
2 one is what the cell looks like, and the other is
3 what the cell is on a blueprint, you know, the DNA.

4 The reason that's important is that, as
5 I said earlier, he was at high -- he is early on at
6 higher risk for central nervous system involvement,
7 hence the need to look in his spinal fluid, hence
8 the need that we would give him medicine that would
9 get into his spinal fluid. That's why that was
10 done. That's why he pointed that out, as did I, in
11 dealing with such a patient you need to know that.

12 Once a person goes into remission it
13 already tells us that the biology of the disease is
14 that it is a sensitive disease, and all these
15 things that predict good, bad or indifferent really
16 are only useful when they walk in the door.

17 Once they've gotten treated and they're
18 now in remission most of those things don't mean
19 anything anymore. In other words, it's a whole set
20 of different circumstances.

21 Q. Even if the patient continues to need
22 transfusion?

23 A. Has nothing to do with that.

24 Q. Has nothing to do with that?

25 A. No, they're in remission. There is no

1 active disease. In other words, if he did not go
2 into remission and his disease did not respond then
3 you can say "Well, he had a monocytic leukemia, a
4 Fab M-5, a risk resistant disease." You know it's
5 a worse disease.

6 In fact it's a bell shaped curve. Some
7 people are going to do well and some don't, and you
8 can shift that curve based on prognostics. The
9 fact that he went into remission quite easily, and
10 that he has remained in remission for two years is
11 -- you know, attests to the fact that he has a
12 sensitive disease. And the fact that his -- that
13 he was needing transfusions is more a reflex of the
14 sensitivity of his normal tissues as well as his
15 malignant cells to the treatment. That's not
16 related to the leukemia.

17 Q. Okay. Like I said, I'm just listening.

18 A. I mean, if you want me to clarify it, if
19 you need additional clarification I'd be happy to
20 provide that for you.

21 Q. Well, my understanding is that someone who
22 presents -- or someone who is diagnosed with acute
23 monocytic leukemia has a more poorer, excuse my
24 terms, poorer prognosis than a person who presents
25 with a leukemia that is related to -- the term you

1 used was lymph- -- lymph- --

2 A. Let me back up. Let me clarify one step
3 at a time.

4 Q. Okay.

5 A. Someone that presents with acute monocytic
6 leukemia is -- is an, in quotes, poor prognosis
7 leukemia, that is correct. That means that it's
8 possible that they may not go into remission, or if
9 they do so they may relapse early. That's clearly
10 the case, okay?

11 Q. All right.

12 A. However, once you go into remission and
13 you stay in remission that falls by the wayside.
14 In other words, if I told you theoretically that
15 you only had a 40 percent chance -- well, I'm
16 making numbers up. Let's say you had a 40 percent
17 chance of going into remission, and you had a 60
18 percent chance you weren't --

19 Q. Right.

20 A. -- based on all the predictors, and you
21 went into remission. For you you're a hundred
22 percent in remission. So once you go in remission
23 those predictors fall out on an individual patient,
24 it's not helpful anymore, you're in remission or
25 you're not. That's what I -- the point I made

1 about being a little bit pregnant.

2 Q. So if the year is the cutoff --

3 A. I can't say a year is a cutoff. I think
4 it -- that's not accurate. The -- this is
5 complicated. The likelihood of someone relapsing
6 after transplant takes all comers, okay?

7 And most of the data that you would
8 look at, at least in our data anyways, it's less
9 common to find someone relapsing, irrespective of
10 what kind of leukemia they had, because I just told
11 you once you go into remission all those things
12 don't -- don't matter anymore.

13 Q. Okay.

14 A. And I'm not making it a black and white
15 you get to 366 days you can breathe a sigh of
16 relief, as opposed to 364 days. It doesn't work
17 quite that way. But the longer you go in remission
18 the less likely you are, especially after a
19 transplant, of having the disease recur.

20 Q. Explain to me what is extramedullary
21 involvement?

22 A. Okay. That's again an organ outside of
23 the bone marrow, the bone marrow and the blood.
24 The leukemia starts, we think, in the bone marrow,
25 and spreads to the blood. And usually the disease

1 will -- well, extramedullary means the disease is
2 now starting to involve organs that are not
3 normally involved with leukemia, for example the
4 lung, that's an extramedullary. "Medullary" is
5 marrow, "extra" outside the marrow. A lung that's
6 filled with leukemia, that would be an
7 extramedullary. And in what context did you use
8 that?

9 Q. Well, the reason I wanted to know is the
10 type of leukemia that Sharad presented with, I want
11 to say the mon- --

12 A. Monocytic leukemia.

13 Q. It's a monocytic variant of ANL?

14 A. That's correct.

15 Q. Okay. Does that carry with it a higher
16 incidence of extramedullary involvement?

17 A. Yes, especially --

18 Q. Okay.

19 A. -- the brain.

20 Q. Are you aware of any data that is
21 available for this type of leukemia in terms of
22 survivability and cure and remission and --

23 A. If we -- if we separate that subset out?

24 Q. Yes.

25 A. If -- if we were discussing Sharad's case

1 three months after his transplant, I think it would
2 be the arguments that you're making are -- are
3 compelling. We don't know, we are basing that he
4 is at high risk, et cetera, et cetera.

5 The fact of the matter is we are now
6 looking at him a year and a half down the road, so
7 most of those things start to fall -- you know,
8 have really fallen out. There are studies --

9 Q. Okay.

10 A. -- that have reported monocytic leukemia
11 as being a poor -- a worse prognosis leukemia.

12 Q. But -- but again that's a factor of time?

13 A. Again it's predicting -- if you asked me
14 in the first quarter who is going to win the
15 football game and I tell you, and then after the
16 game is over you're going to ask me who is going to
17 win the football game, I think that they obviously
18 have different significance if we talk about a
19 prognosis.

20 Q. Yes, but I guess what I'm asking is when
21 is the game over with Sharad?

22 A. Well, what I'm trying to tell you is that
23 in my opinion, and based on the opinion of others,
24 that getting a year and a half out after transplant
25 is in my -- is tantamount to the game being over.

1 I mean, maybe -- maybe there are ten seconds left
2 to go or something along those lines, but it's
3 pretty near the end, I mean as far as the cutoff of
4 -- of feeling certain that the likelihood of the
5 leukemia coming back is quite small. It's not
6 zero, but it's small.

7 Q. Are you aware of any studies out there
8 which -- I mean from reputable centers, you know,
9 I'll name some of them, University of Michigan,
10 Indiana University, University of Chicago, which
11 disagree with that?

12 A. Which disagree with what?

13 Q. With what -- in terms of a long-term
14 prognosis with a patient -- with patients who
15 present with a monocytic variant of ANL in terms of
16 survivability, relapses, all that?

17 MR. SCANLON: Well --

18 THE WITNESS: There are lots of
19 studies. I think probably Minnesota, there is
20 Stanford, and we can start listing centers. Again,
21 many of the centers will report -- let's say you
22 report a hundred patients, and fifty relapse or
23 fifty are in remission, okay?

24 I mean, I'm not debating that there is
25 a possibility that these things can happen; but if

1 we take -- if we follow the guy that's in remission
2 and he goes two, three, four years, then I don't
3 care what his prognosis was. If he's not relapsed,
4 then he's not relapsed.

5 I mean, I -- there is literature -- if
6 you want I can get some more information and we can
7 look over the histologic variant as far as a
8 predictor and how those people fair, but the fact
9 is that if they're still in remission it doesn't
10 matter what their risk was, they're doing well.

11 Q. Do you think the events as you understand
12 what occurred at St. Thomas, not so much the events
13 but Sharad's current condition, does that have any
14 effect upon prognosis, in your mind?

15 A. I'm not sure I understand.

16 MR. SCANLON: The fact he's in a
17 semi-vegetative state?

18 MR. MARMAROS: Yes.

19 THE WITNESS: The fact that he's in a
20 semi-vegetated state, is that interfering in any
21 way with what?

22 MR. TREADON: Does it impact?

23 BY MR. MARMAROS:

24 Q. Does it impact, does it improve, does it
25 not, or how does it have any impact on his

1 prognosis, if any?

2 A. Well, I'm not an expert in -- in the coma
3 vigil or persistent vegetative state, or the terms
4 whatever a neurologist would use. I'm not a
5 neurologist. I don't know if he's at higher risk
6 for thromboembolism, pneumonias. I mean, I can't
7 really render an opinion as far as --

8 Q. I mean --

9 A. -- as far as he's not active.

10 Q. I don't want to ask you that.

11 A. His life expectancy is diminished.

12 Q. As it relates to the leukemia.

13 A. As relates to the leukemia, I'm not aware
14 of any studies where one can look at that.

15 Q. Like a lower metabolism rate, would that
16 have any impact, for example, in your mind on --

17 A. I'm not sure he has a lower metabolism. I
18 mean, he's not -- I don't know what his MET -- I
19 don't know there is any data that says lower
20 metabolism influences leukemia in any way,
21 otherwise we'd be treating leukemia with thyroid
22 medications and the like rather than cytotoxic
23 drugs.

24 Q. Okay. Doctor, there was a bone marrow
25 aspiration and biopsy done on September 19th of '92

1 which showed "Patchy cellularity five to fifty
2 percent with hypoplasia involving all three cell
3 lines." You wouldn't have that? I'm sorry, I
4 thought you did.

5 A. I have that report if you'll permit me --

6 Q. Sure.

7 A. -- to refer to it, I did see it. It's in
8 here somewhere.

9 MR. SCANLON: Are you talking about
10 '91?

11 MR. MARMAROS: It must be '91. I'm
12 reading from my notes.

13 THE WITNESS: It's September, 1991.
14 Yes, I have that note.

15 BY MR. MARMAROS:

16 Q. Okay. Now, this -- if I'm not
17 misunderstanding, okay, this -- this finding
18 despite the fact that it's felt that Sharad's in
19 complete remission at that time?

20 A. I -- I'm confused. This -- this report
21 really reflects the fact he has no active leukemia.

22 Q. Okay. I'm going from notes,
23 unfortunately, but the fact that --

24 A. Well, I can read you the report.

25 Q. Go ahead if you would, because I don't

1 have all the records here.

2 A. What is done in these cases is they always
3 make a comment as to whether they -- how many
4 blasts, leukoblasts they see. And under -- on the
5 first page of that the pathologist says, "Blasts
6 comprise less than five percent of cells seen by
7 definition." That's less -- that's not leukemia.
8 Would you like to look at the report?

9 Q. Could I?

10 A. This is what I read, right here where my
11 thumb is.

12 Q. What is it -- can you explain that to me,
13 I'm sorry, "blasts comprise less than five percent
14 of cells"?

15 A. One of the definitions of leukemia or
16 leukemia relapse is having more than five percent
17 blasts in the bone marrow.

18 Q. Okay.

19 A. And they -- the pathologist put in there
20 -- put in there indicating that there aren't more
21 than five percent blasts, meaning there is no
22 active leukemia as far as they can tell in that
23 sample.

24 Q. Okay. Go to the second page though and
25 explain that, if you would, to me where it says

1 under cellularity.

2 A. Okay. This is a marrow that's still
3 growing back.

4 Q. It says --

5 A. "Cellularity was quite variable," meaning
6 some of the areas of the bone marrow had grown back
7 normally, some of the areas of the bone marrow were
8 still regenerating from the cells we had put in
9 previously, and that's why there is a marked
10 variation.

11 The biopsy clot -- I'm sorry, the
12 aspirant clot describes the cellularity as being
13 twenty to fifty percent, and the -- the core
14 biopsy, the actual biopsy -- again these are
15 complimentary pieces of data -- varied from five to
16 forty percent. So there are areas that were
17 normally grown back and areas that were still
18 thinned out because they hadn't grown back yet.

19 Q. I'm sorry, bear with me if you can. Where
20 it says "Patchy" on there --

21 A. Yes --

22 Q. -- "With patchy cellularity" --

23 A. -- yes --

24 Q. -- "five to fifty percent" --

25 A. -- yes.

1 Q. -- "with hypoplasia involving all three
2 cell lines," what does that mean?

3 A. That means that the bone marrow hasn't
4 grown back completely. Some of the areas that --
5 there are three major cells in the bone marrow,
6 three types of cells, and in the blood. There are
7 the red blood cells that carry oxygen --

8 Q. Okay.

9 A. -- the white blood cells that fight
10 infection --

11 Q. Platelets?

12 A. -- and platelets that aid in coagulation.

13 When someone says tri-lineal hypoplasia
14 that means three, tri. The red cells haven't grown
15 back completely, the white cells haven't grown back
16 completely, the platelets haven't grown back
17 completely. That's a descriptor that says the bone
18 marrow is still thinned out.

19 I'm not sure why you're confused. Can
20 you tell me what information --

21 Q. Well, because I interpreted that as being
22 sort of -- sort of being contra to being that the
23 fact that the patient was in complete remission at
24 that time. I mean, that -- that set of
25 interpretation that the patient that the

1 cellularity was patchy with -- and I won't restate
2 -- it was sort of contra to the patient being in
3 complete remission at that time. And if it's not,
4 it's not.

5 A. I'm not sure exactly what your confusion
6 is other than when we say someone is in remission
7 do they have to have the marrow grow back? If
8 that's what you're asking me, they have to have --
9 at the time the blood counts still weren't --
10 weren't totally normal, and the bone marrow had not
11 grown back completely.

12 So if you're asking me does this
13 fulfill the definition, at this point in time I
14 would have to say no because the blood counts
15 hadn't come back yet. I mean, they're still
16 borderline low. But this is only two months -- not
17 even two months after the transplant.

18 Q. Okay.

19 A. But there is no leukemia demonstrated at
20 this point, and subsequently my understanding is
21 there has never been leukemia demonstrated in this
22 patient subsequently.

23 Q. From your records when did the -- did you
24 begin the intrathecal methotrexate treatment?

25 A. I think we began that -- I think we only

1 gave him a few courses because we were concerned
2 about suppressing his marrow further. I don't
3 think he had a lot of intrathecal methotrexate
4 treatments. I think he only received a few in the
5 hospital and a few in the ambulatory area.

6 That was one of the reasons that we
7 gave him the consolidation treatment with high
8 doses of -- of cytosine arabinoside. That's a
9 medication we have published and demonstrated
10 excellent central nervous system transference. If
11 you give it by vein, that drug goes right in the
12 brain, even if you give it by vein. That's very
13 effective in preventing of disease, as well as
14 sticking the medication right into the spinal
15 fluid.

16 I don't recall exactly how many
17 intrathecal treatments of chemotherapy he had, I'd
18 have to dig that out. I don't have that at my
19 fingertips.

20 Q. Okay. In your June 24th, '91 transmittal
21 there is reference to Sharad contracting hepatitis
22 B, June 24th of '91.

23 A. Yes, I have that. Now, this is my note?

24 Q. Is it -- I didn't look who sent it. I
25 think you signed it.

1 A. Yes, I signed it. Okay. Now, I said --

2 Q. Go ahead and read it because I just want
3 to get an understanding of it if I can.

4 A. I believe -- okay. I'm not sure -- well,
5 let me -- let me read this note out loud if you
6 will. Let's see, well, I said -- I said here I saw
7 Sharad -- I'm paraphrasing now.

8 Q. Sure, go ahead.

9 A. Pardon?

10 Q. Paraphrase, go ahead.

11 A. Oh. I said I saw Sharad on June 24th,
12 1991. He was diagnosed in December of 1990, he
13 achieved a complete remission and he received
14 intensive consolidation with cytosine arabinoside.
15 He was to undergo a marrow transplant and harvest
16 in May of '91, but insufficient marrow was obtained
17 at that admission. He underwent a second marrow
18 harvest in June of '91.

19 He comes in today to undergo marrow
20 examination in anticipation of marrow harvest
21 procedure scheduled for June 28th. We arranged for
22 him to donate two units of whole blood as an
23 outpatient.

24 I received notification from the
25 American Red Cross that one of his own units is

1 reactive for hepatitis B surface antigen. This was
2 of concern since when I saw him on May 23rd that he
3 had a negative hepatitis surface antigen --
4 negative hepatitis C antigen on May 30. It is not
5 clear to me whether this is a recent finding or
6 artifact. Essentially I'm saying that he is now
7 surface antigen positive liver -- hepatitis
8 positive.

9 I have asked -- again I am skipping
10 over this letter.

11 Q. Sure.

12 A. I asked Dr. Fred Webber of our G.I.
13 service to consult on this patient when he's
14 admitted on Thursday, June 27th, 1991. The regimen
15 that we plan to use is that of busulfan -- this is
16 for the transplant -- busulfan and
17 cyclophosphamide. This regimen is highly effective
18 in the treatment of leukemia as well as hepatic
19 veno occlusive disease and hemorrhagic cystitis,
20 and I give this reference in that article to Mr.
21 Scanlon, busulfan stroke cyclophosphamide, but was
22 not -- but was associated with increased incidence
23 of hepatic veno occlusive disease, but there was no
24 indication that other conditions such as hepatitis
25 B surface antigen positivity was a risk factor.

1 Then I cited another reference. A
2 recent review from the Fred Hutchinson Cancer
3 Research Center in Seattle indicated patients
4 positive with surface B antigen were not at
5 increased risk for increase of severe liver disease
6 after transplant. In fact, the group of patients
7 reported in that series -- and I give the reference
8 -- underwent allogeneic bone marrow transplant at
9 the start of the test and had no incidence of liver
10 hepatic failure. So basically I said that, you
11 know, that shouldn't be a problem and I wasn't --

12 Q. Where did it come from, that's what --

13 A. Where did it come from, the hepatitis?

14 Q. The hepatitis B.

15 A. That's a good question. I didn't know at
16 the time I saw him. As you know there is an
17 incubation period, and it's conceivable that he got
18 it from a contaminated unit, that it -- resulting
19 in a subclinical infectious hepatitis infection,
20 and that's what we are left with.

21 Where did it come from, I don't know.
22 All of our donors are screened. He got blood in
23 Akron, which presumably was also screened, and
24 people can be in the so-called window period where
25 a donor may actually be infectious but would test

1 negative.

2 Q. Okay. It's not related though in any
3 event to -- absent the blood transfusion to the
4 leukemia itself?

5 A. There is no relationship between --

6 Q. Okay. And is --

7 A. -- infectious hepatitis and leukemia if
8 that's what you're asking me.

9 Q. Okay.

10 A. In fact, in the older studies the patients
11 with leukemia who got infectious hepatitis actually
12 did a lot better than the ones that didn't, and the
13 message there isn't that it's good to get
14 infectious hepatitis. It's if you live long enough
15 with leukemia and you get enough transfusions
16 you'll eventually get hepatitis. So that's not a
17 related event.

18 Q. And you don't -- and that study supports
19 -- and I have to look it up myself, obviously, but
20 that study supports the fact that's not going to
21 have an impact on his prognosis?

22 A. That's why -- I think you're getting the
23 message from a pretty straight guy.

24 Q. I understand.

25 A. When I make a statement I make the

1 references to corroborate that statement.

2 Q. Doctor, if I give you a piece of paper --
3 and I hope I'm using the right terminology -- can
4 you plot out for me a survival curve for Sharad, I
5 mean upon presentation, and extend it out to
6 however long a period of time you would like? Do
7 you know what I mean by a survival curve?

8 A. Yes, I know what a survival curve is, but
9 that usually is a population, survival curves like
10 Kaplan-Meier or a survival -- actuarial survival
11 curve, in other words percent surviving on a
12 horizontal axis, and time -- I'm sorry, percent
13 surviving on the vertical axis and the time on the
14 horizontal axis.

15 Q. Okay. But can't --

16 A. I mean, that's what -- you usually do that
17 for hundreds or, you know, populations of patients.

18 Q. Don't you do that for populations of
19 patients who present with acute myositic --

20 A. Yes --

21 Q. -- leukemia?

22 A. -- yes.

23 MR. SCANLON: What he's saying, you
24 don't do it for one patient.

25 MR. MARMAROS: But Sharad --

1 THE WITNESS: Each particular patient
2 -- each mark on the curve is a patient.

3 BY MR. MARMAROS:

4 Q. Wouldn't Sharad be a member of that
5 general population? I'm wondering if you can
6 present for me, or draw for me, or give me a
7 survival curve for that type of patient who
8 presents with that type of condition, the same as
9 Sharad when he presented, someone -- someone who
10 has acute myositic leukemia?

11 A. Acute myo- -- sure.

12 Q. Monocytic leukemia, I'm sorry?

13 A. Acute monocytic leukemia, I don't know if
14 -- I'd have to think about the possibility, the --
15 again, that's a probability though. That's just
16 the probability that -- well, he would be -- he
17 would be on that curve. I mean, he would be out a
18 year -- two years out on that curve.

19 Q. Well, but do you plot those -- do you plot
20 those out for five years?

21 A. You plot them out, I just showed you the
22 slide, for 20 years, 25 years, 30 years. I mean,
23 they go on as long as the curve is, as long as the
24 last patient on the curve. If you're doing a study
25 for two years, the curve is two years long. And if

1 you've -- I just showed you that curve that went
2 out to 15 years. It's going to go as long as the
3 last patient -- the patient who is on the study the
4 longest, or who is in that cohort of patients the
5 longest, that will -- that curve could go 50 years.

6 Q. I understand it's like liver transplants.

7 A. Right.

8 Q. But my -- my point is, and I'd like to see
9 if I can start with your starting date, and if we
10 can take someone like Sharad, who presents with
11 that type of condition, the acute monocytic
12 leukemia, and sure, some of it is retrospective, we
13 may know some of the answers, but I'm wondering if
14 you can plot that out for me in a survival curve,
15 is that possible?

16 A. Off the top of my head I don't think I
17 could -- I could really do that.

18 Q. Well, I mean, with -- with the factors
19 that we know, that he has acute monocytic leukemia,
20 that it was not -- well, it may not be important,
21 autologous -- I mean all the factors that present
22 with Sharad, can't we plot those out with the
23 survival curve?

24 A. You're asking me to off the top of my head
25 come up with a multi-variant analysis with a

1 probability -- either a Kaplan-Meier or an
2 actuarial survival curve, and I think it would be a
3 big guess on my part. I couldn't sit here and draw
4 you a curve like that.

5 Q. All right. If I understand those curves,
6 there are two ways to do those curves, it would be
7 a survival curve and also a disease free?

8 A. Yes, there are a number of ways to do
9 those curves. You can do event free survival,
10 disease free survival, overall survival. Are you
11 going to estimate the probability of survival, are
12 you going to have actuarial survival? I mean,
13 there is a whole statistical literature.

14 That's why -- I'm not trying to be cute
15 about it, but it is really, you know, quite complex
16 depending on what interventions have been
17 undertaken. The survival of acute monocytic
18 leukemia patients by in large is not great, hence
19 we put them into the bone marrow transplant group.

20 Q. Okay.

21 A. And bone marrow transplant is a very
22 powerful tool and good tool and may offset the fact
23 that he had a poor prognosis. In other words, if
24 you have the right tools to get rid of the disease
25 that -- that is the way to go. That's -- that's

1 how -- that's generally how it's done.

2 In other words, if you knew someone was
3 already cured if he had it, let's say he had a kind
4 of leukemia and there are not too many of these,
5 let's say there was a leukemia that you knew that
6 -- childhood leukemia for example, okay, you
7 brought this up earlier.

8 Q. Yes.

9 A. There are subsets of childhood leukemia
10 patients that we know that they do so well if it's
11 a girl, and it's between the ages of three and ten,
12 and it's got a low white count at admission and
13 doesn't have a mediastinal mass, doesn't have a big
14 spleen, doesn't have an L cell phenotype, is CAL
15 positive mass, normal immunoglobulin -- I can list
16 about 30 different things -- you can create a
17 patient or patients and say these kids are going to
18 do so well that 90 percent plus are going to be
19 cured with standard therapy.

20 If you knew that you wouldn't put a --
21 a very low risk patient, low risk for relapse, into
22 a bone marrow transplant. In other words, if
23 you're going to cure -- let's say if you're going
24 to cure 90 percent of the patients the benefit of a
25 transplant is probably not -- it's probably not

1 going to help you, you're going to be transplanting
2 people that are already cured.

3 On the other hand you take people that
4 are at very high risk for relapse, who with
5 standard therapies aren't going to do well, get
6 them into good shape, demonstrate they have disease
7 sensitivity and then give your best therapy which
8 is -- which is -- has a morbidity and mortality
9 associated with it and transplant those people, in
10 those people you have changed the natural history
11 of the disease.

12 I just told you that formerly they were
13 poor prognosis. If you get them into remission and
14 now give them a curative therapy it ain't the same
15 any more, all bets are off because now you're
16 giving them a potentially curative therapy at a
17 time when they're in good shape, and you will have
18 altered the natural history. So that's why it's
19 difficult to do what you're suggesting.

20 Q. Well, maybe I'm -- maybe I'm analogizing
21 to like a breast cancer case but, you know, they
22 can find no lymph node involvement, they can do
23 anything they want --

24 A. Okay.

25 Q. -- 15 years from now.

1 A. That's absolutely right.

2 Q. It's right back there.

3 A. We can talk about diseases like breast
4 cancer. Breast cancer, we talk in terms of ten
5 year disease free survival in breast cancer. We
6 realize women relapse 15, 20, 30 years later. It's
7 common in breast cancer, women have two breasts,
8 the phenomena is metachronous primarily, whatever
9 led a woman to get cancer in this breast. When you
10 treat people with breast cancer you don't do
11 anything about the physiology or the makeup of that
12 patient. How do you know that those same factors
13 that led to the development of cancer in this
14 breast didn't lead to the development of something
15 starting in the other breast.

16 And in fact in breast cancer we don't
17 really know, we don't have the studies in breast
18 cancer that say by a certain period of time you get
19 well, beyond a certain period of time you're okay
20 or not okay. That's true in that disease.

21 On the other hand there are diseases
22 like certain kinds of lymphoma, germ cell tumors,
23 where we can say if you go beyond certain periods
24 of time the likelihood of you having disease
25 recurrence is extremely small. Germ cell tumors,

1 if you go a year after a germ -- I'm talking
2 testicular tumor --

3 Q. I understand.

4 A. -- a year after completing your treatments
5 in testicular cancer very, very, very small
6 likelihood of having disease recurrence. And in
7 fact at the University of Indiana their series are
8 such if you go two years it's almost unheard of to
9 have disease recur after two years. Similar data
10 for Burkitt's lymphoma once you've gotten
11 treatment.

12 So if there are disease models where we
13 know with very narrow confidence levels if you have
14 disease that stays inactive for a period -- finite
15 period of time, the likelihood of cure is very good
16 and we probably say they're cured. Other diseases
17 we are not so sure, and breast cancer is probably
18 the most striking example.

19 I think that we are dealing with a
20 situation -- a former rather than a latter
21 situation in the transplant. It's less likely that
22 somebody will relapse once they're in remission
23 once they get transplant therapy and once they stay
24 in remission.

25 Q. Okay. Bear with me, I just have a few

1 more.

2 In your May 29th, '91 letter you talk
3 about how you discuss with the parents the risks
4 and benefits of autologous -- or the risks versus
5 benefits of autologous bone marrow transplant?

6 MR. TREADON: What date?

7 MR. MARMAROS: March 29th.

8 THE WITNESS: Give me a second. Which
9 letter is this?

10 BY MR. MARMAROS:

11 Q. Sure. March 29th, '91, it's just a one
12 sentence thing. You talked about how you discussed
13 with the parents --

14 A. March, '91?

15 Q. Yes. March 29th, I believe.

16 A. Oh, gee.

17 Q. Page two, Doctor, second full paragraph.

18 A. March 29th, okay. I again discuss the
19 risks and benefits of an autologous bone marrow
20 transplant with the patient and his mother.

21 Q. I just want to know what they are, the
22 risks.

23 A. Oh, the risks of the transplant?

24 Q. Yes.

25 A. Well, we had him sign a consent form for

1 one thing which describes, you know, in lay
2 language. But again the risks of a transplant are
3 probably a little more substantive but similar to
4 what is -- what are the risks for conventional
5 chemotherapy, infection being first and foremost,
6 bleeding or hemorrhagic manifestations, the
7 potential for damage to the liver. Again, these we
8 believe to be reversible or we couldn't perform
9 this therapy. Damage to the lungs, some bladder --
10 damage to the bladder, those are the main risks.

11 There are, of course, other -- other
12 risks, allergic reactions, the failure of the bone
13 marrow to -- to grow properly and -- and/or the
14 failure of the -- the transplant to eliminate the
15 leukemia. Those are sort of --

16 Q. Okay.

17 A. That's encapsulated.

18 Q. May 23, '91 you wrote in there, and I'll
19 paraphrase for you --

20 A. Please.

21 Q. -- that you gave Sharad at that time an --
22 approximately a fifty percent long-term disease
23 free survival.

24 A. May --

25 Q. 23 of '91. First page, the last full

1 paragraph.

2 A. Gee, unfortunately I don't have that
3 letter. I go from --

4 Q. Here, you can use mine.

5 A. Can I use yours?

6 Q. Sure.

7 A. It's probably in the other chart. Okay.
8 Okay, that's the data I'm quoting from our ECOG
9 study.

10 Q. Okay. When does that change?

11 A. I'm sorry, I don't follow your question.

12 Q. Okay.

13 A. I'm having problems this time.

14 Q. That's okay. At this point in time you
15 gave Sharad approximately a fifty percent -- I
16 don't want to misquote you -- a fifty percent.
17 What did you say in the letter, a fifty percent --

18 A. I guess --

19 Q. Okay.

20 A. -- long-term disease free survival.

21 Q. Your percentages on the disease obviously
22 changed. I want to know when it changed, at what
23 point in time?

24 A. It changed because he hadn't done the
25 transplant yet. What I was saying, out of a

1 hundred Sharad Lals brought in to my office in
2 first remission, if we were subsequently to do a
3 bone marrow transplant that half of them would
4 eventually relapse or whatever, die of the
5 treatment, succumb to the disease, and
6 approximately half of them would stay in remission,
7 okay?

8 Now we have one of those, one of those
9 Sharads. We take and we say "Okay, where is he?"
10 Well, he's still in remission a year and a half
11 after his transplant.

12 Q. Okay.

13 A. That's why I think --

14 Q. I guess that's what -- that's what I --
15 I've probably never fully understood is two and a
16 half years after remission, is that where you can
17 safely say in your mind that that --

18 A. There are --

19 Q. Is there a distinct cutoff point in which
20 you can say he progresses from not having a chance
21 -- a significant risk of having a relapse to having
22 a risk?

23 A. I don't think that it's -- I don't think
24 it's ever black and white. I think it's -- it's a
25 series of probabilities at all times. I mean, we

1 are -- you know, we are always faced with
2 probabilities. The more patients you have in a
3 study, the longer they're followed, the more
4 information you have, the greater the certainty, in
5 other words, the narrower the confidence interval
6 you can say.

7 But that is again only useful when you
8 talk about populations of patients. Anyone who is
9 on a curve who is out a ways is probably a
10 different patient than someone who is just
11 starting.

12 Q. How far out a ways do you have to be in
13 the curve, that's all I want to know?

14 A. How far out a ways? Our own data would
15 probably suggest a year and a half to two years is
16 pretty good.

17 Q. Okay.

18 A. I will provide you with -- I will -- I
19 can't promise I'll get it to you tomorrow.

20 Q. That's okay. I can't promise you I'll
21 read it tomorrow either.

22 A. I will get you a large series. I'll again
23 point out to you there are two issues here of note.
24 One, if you look at people who did not undergo a
25 bone marrow transplant in leukemia that there

1 probably is not this -- this window that I've
2 described. In other words, if you look at people
3 who have leukemia who didn't get a transplant,
4 those people may continue to relapse down the road.
5 This is not seen in the transplant group, that
6 there is something about that therapy.

7 Q. Is there something about that category of
8 people that --

9 A. There is something about those people that
10 you have changed the natural history of the
11 disease. That's the point I'm trying to make, that
12 really throws things --

13 Q. Okay.

14 A. -- into a different level. And the second
15 thing is, again, it's a frustrating concept but
16 you're always -- there is always a probability and,
17 you know, for any one individual you just don't
18 know whether they're going to be a zero or a one.
19 In fact, it really comes down to a binary thing.
20 So that's a tough concept. I'm not trying to be
21 evasive.

22 Q. I'm not suggesting you are. On your
23 curriculum --

24 A. This is yours.

25 Q. -- on your curriculum vitae you have a

1 number of articles that you've authored. Are any
2 of the articles that you authored on point in terms
3 of the subject matter we have been talking about?

4 A. Yes.

5 Q. Prognosis?

6 A. Oh, on prognosis for leukemia?

7 Q. Yes.

8 A. Prognosis, I think indirectly. I don't
9 think that's been my focus. My main focus is
10 treatment as opposed to prediction.

11 Q. Why don't you, if you can, if you can just
12 read them by number off your CV in terms of which
13 articles are on point?

14 A. Say again. You have my current CV.

15 Q. I don't think I do, but --

16 A. I just gave it to you.

17 MR. TREADON: Here it is. There were
18 120.

19 BY MR. MARMAROS:

20 Q. Are we talking about like nine percent of
21 these articles are on --

22 A. I'm a transplanter. Most of my career is
23 in terms of treatment --

24 Q. Okay.

25 A. -- with the results of what happens as

1 opposed to predicting how it's -- in other words
2 playing the game as opposed to --

3 Q. Okay.

4 A. -- forecasting before the game.

5 Q. Okay.

6 A. I have a -- you know, I have a fairly long
7 publication.

8 Q. I'm not going to ask you on 21 articles,
9 obviously. I want to know if there are one or two
10 articles that -- that you considered to be --

11 A. Relevant to him?

12 Q. Yes, relevant or representative of what we
13 have been talking about.

14 A. Okay. This last article here, this one on
15 page -- let's see, our ECOG experience, page --
16 what is it?

17 Q. 27?

18 A. 13.

19 Q. Okay. It's number 120?

20 A. Number 119.

21 Q. 119?

22 A. Uh-huh.

23 Q. This is my last question, and if you've
24 answered this already you'll tell me and I won't --
25 and I'll be satisfied with that. In terms of -- of

1 quality of life down the road was Sharad, although
2 being in remission, what -- what does he have to
3 look forward to as relates to the leukemia in terms
4 of treatment, et cetera?

5 A. Well, when we undertake a transplant it's
6 with the understanding that this is the final
7 insult, if you will. In other words, if -- if you
8 get somebody into as low a tumor burden as possible
9 to reduce the leukemia so it's no longer
10 measurable, keep treating it, get it to the lowest
11 level, come in with very intensive treatment with
12 the hope and the realization in some patients you
13 eliminate the disease and it will never come back.
14 If we are successful in doing that he should have
15 been restored to a productive, full life in the
16 community, going on to college and going on to
17 pursue whatever he wanted to do.

18 Q. My question is, is in terms of your
19 involvement with that type of patient, I mean, does
20 he come back to you on a yearly basis, do you --

21 A. Oh, he would -- we would probably
22 gradually lengthen the interval. And again, as I
23 stated earlier, we interact with the referring
24 physician. There are still patients that -- that
25 -- I mean, I don't want -- I don't know if I should

1 name names --

2 Q. No, you shouldn't.

3 A. -- in a deposition.

4 Q. You shouldn't.

5 A. But there are patients, that we followed
6 with Dr. Mubashir, who come back to see us on a
7 twice a year basis who are fairly far out in their
8 disease. They see them, we see them. You know, we
9 still keep following them. They always need to be
10 under the peripheral care perhaps at this point of
11 -- of a -- of someone in that regard.

12 Q. Who is Sharad's current physician who is
13 fulfilling a role of Dr. Mubashir at the current
14 time?

15 A. You mean right now --

16 Q. Yes --

17 A. -- at this point in time?

18 Q. -- yes.

19 A. I'm not aware. I understood it was Dr.
20 Hazra. Is that not the case, or is that accurate?

21 DR. LAL: Yes, Dr. Hazra is following.

22 THE WITNESS: Dr. Hazra.

23 DR. LAL: You know, basically things
24 have changed since this incident.

25 MR. TREADON: I understand that.

1 MR. MARMAROS: I understand.

2 BY MR. MARMAROS:

3 Q. It's Dr. Hazra?

4 DR. LAL: And Dr. Madlin. H-a-z-r-a.
5 Madlin is M-a-d-l-i-n. She's a neurologist.

6 MR. MARMAROS: Okay. Fine, thank you.
7 Do we -- this is off the record -- well, are you
8 done? I'm sorry.

9 - - -

10 BY MR. TREADON:

11 Q. Just, believe it or not, I have a couple
12 more questions. But really just a couple more.

13 Mr. Marmaros was asking you about
14 drawing a curve, a survival curve. I think you
15 answered this, but when do you go from a reasonable
16 degree of medical certainty that there is a cure?
17 Is there a -- is it a year or is it two years or is
18 it a year and a half or -- or can you give me a --

19 A. Well, I don't think -- I don't think there
20 have -- I don't think you can do that with a high
21 degree of certainty. I think you can infer based
22 on data. Our own data are such that a year, a year
23 and a half in remission after transplant --

24 Q. Okay.

25 A. -- is pretty good. We have seen very few

1 relapses after that point. I did not say we saw
2 none, but we saw few.

3 Q. I understand. What is your degree of
4 certainty right now, 90 plus percent, 80 plus
5 percent?

6 A. Certainly more than -- I would say it's
7 probably in that range, somewhere around there.

8 Q. 90 plus?

9 A. 80, 90 percent, something like that.

10 MR. TREADON: That's all. Thank you.

11 Bill, if you could keep this, make it a
12 part of this record.

13 Doctor, I'd like to have you read this
14 if it's typed.

15 THE WITNESS: I plan on reading it.

16 MR. TREADON: Okay.

17 - - -

18 (Deposition concluded at 4:00 o'clock p.m.)

19 - - -

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I, HILLIARD M. LAZARUS, M.D., do
verify that I have read this transcript consisting
of ninety-one (91) pages and that the questions and
answers herein are true and correct with
corrections as noted on the errata sheet.

HILLIARD M. LAZARUS, M.D.

Sworn to before me, _____,
a Notary Public in and for the State of _____,
this _____ day of _____, 19__.

Notary Public in and for the
State of _____.

My commission expires _____.

C E R T I F I C A T E

STATE OF OHIO,)

) SS:

SUMMIT COUNTY.)

I, William S. Bish, RPR/CM and Notary Public within and for the State of Ohio, duly commissioned and qualified, do hereby certify that the within named witness, HILLIARD M. LAZARUS, M.D., was by me first duly sworn to testify the truth, the whole truth and nothing but the truth in the cause aforesaid; that the testimony then given by the witness was by me reduced to Stenotypy in the presence of said witness, afterwards transcribed upon a computer; and that the foregoing is a true and correct transcription of the testimony so given by the witness as aforesaid.

I do further certify that this deposition was taken at the time and place in the foregoing caption specified, and was completed without adjournment.

I do further certify that I am not a relative, counsel or attorney of either party, or otherwise interested in the event of this action.

IN WITNESS HEREOF, I have hereunto set my hand and affixed my seal of office at Akron, Ohio on this 6th day of January, 1993.



William S. Bish, RPR/CM and Notary
Public in and for the State of Ohio.

My Commission expires November 4, 1994.

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