

<p>1</p> <p>2 IN THE COURT OF COMMON PLEAS</p> <p>3 OF CUYAHOGA COUNTY, OHIO</p> <p>4 -----</p> <p>5 BESSIE M. BROOKS, etc.,</p> <p>6 Plaintiffs,</p> <p>7 vs Case No. 397309</p> <p>8 Judge McCafferty</p> <p>9 THE CLEVELAND CLINIC</p> <p>10 FOUNDATION,</p> <p>11 Defendant.</p> <p>12 -----</p> <p>13 DEPOSITION OF STANLEY P. BALLOU, M.D.</p> <p>14 WEDNESDAY, NOVEMBER 22, 2000</p> <p>15 -----</p> <p>16 Deposition of STANLEY P. BALLOU, M.D., a</p> <p>17 Witness herein, called by counsel on behalf of</p> <p>18 the Plaintiff for examination under the statute,</p> <p>19 taken before me, Vivian L. Gordon, a Registered</p> <p>20 Diplomate Reporter and Notary Public in and for</p> <p>21 the State of Ohio, pursuant to agreement of</p> <p>22 counsel, at the offices of MetroHealth Medical</p> <p>23 Center, 2500 MetroHealth Drive, Cleveland, Ohio,</p> <p>24 commencing at 8:30 o'clock a.m. on the day and</p> <p>25 date above set forth.</p> <p>-----</p>	<p>1</p> <p>2 -----</p> <p>3 (Thereupon, BALLOU Deposition</p> <p>4 Exhibits 1 thru 4 were marked for</p> <p>5 purposes of identification.)</p> <p>6 -----</p> <p>7 STANLEY P. BALLOU, M.D., a witness herein,</p> <p>8 called for examination, as provided by the Ohio</p> <p>9 Rules of Civil Procedure, being by me first duly</p> <p>10 sworn, as hereinafter certified, was deposed and</p> <p>11 said as follows:</p> <p>12 EXAMINATION OF STANLEY P. BALLOU, M.D.</p> <p>13 BY MR. MISHKIND:</p> <p>14 Q. Doctor, state your name for the</p> <p>15 record, please.</p> <p>16 A. Stanley P. Ballou.</p> <p>17 Q. You are a physician employed at</p> <p>18 MetroHealth Medical Center; true?</p> <p>19 A. That's true.</p> <p>20 Q. Do you have a CV that would be handy?</p> <p>21 A. Yes, I can have my secretary provide</p> <p>22 one for you.</p> <p>23 Q. Is that the young lady seated out at</p> <p>24 the computer?</p> <p>25 A. Right.</p> <p>Q. Do you think you could ask her to</p>
<p>1</p> <p>2 APPEARANCES:</p> <p>3 On behalf of the Plaintiff</p> <p>4 Becker & Mishkind Co., L.P.A.</p> <p>5 By: HOWARD D. MISHKIND, ESQ.</p> <p>6 Skylight Office Tower</p> <p>7 1660 W. 2nd Street Suite 660</p> <p>8 Cleveland, Ohio 44113</p> <p>9 216-241-2600</p> <p>10 On behalf of the Defendant</p> <p>11 Reminger & Reminger</p> <p>12 BY: THOMAS B. KILBANE, ESQ.</p> <p>13 113 Saint Clair Avenue, N.E.</p> <p>14 Cleveland, Ohio 44114-1273</p> <p>15 216-687-1311</p> <p>16</p> <p>17</p> <p>18</p> <p>19 -----</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1</p> <p>2 print one out?</p> <p>3 (Recess had.)</p> <p>4 Q. We went off the record and my</p> <p>5 understanding is that your secretary, or your</p> <p>6 substitute secretary is going to try to find a</p> <p>7 copy of your CV?</p> <p>8 A. Right. I have an old outdated copy in</p> <p>9 my office if she can't find one. It's not up to</p> <p>10 date, but I can give you that.</p> <p>11 Q. How long have you been at Metro?</p> <p>12 A. Twenty-seven years.</p> <p>13 Q. Were you affiliated with a different</p> <p>14 hospital before you came to Metro?</p> <p>15 A. No.</p> <p>16 Q. Where did you do your training?</p> <p>17 A. Medical school at the University of</p> <p>18 Pittsburgh.</p> <p>19 Q. I have had a chance before the</p> <p>20 deposition began to look at your file in an</p> <p>21 effort to try to determine what it is that you</p> <p>22 have reviewed for purposes of your opinions in</p> <p>23 this case.</p> <p>24 As I understand it, when you prepared</p> <p>25 your report, you had the medical records for</p> <p>Mr. Brooks and expert reports of Drs. Eisner,</p>

<p style="text-align: right;">5</p> <p>1 Dineen and Preston; true?</p> <p>2 A. That's correct.</p> <p>3 Q. I believe you also had the autopsy?</p> <p>4 A. That's correct.</p> <p>5 Q. Subsequently, you have been provided</p> <p>6 with a copy of the deposition of Dr. Preston?</p> <p>7 A. That's right.</p> <p>8 Q. And a copy of a report from a nursing</p> <p>9 expert, Mary Jane Smith, most recently; right?</p> <p>10 A. That's right.</p> <p>11 Q. I want to identify a couple items on</p> <p>12 the record before we start going into the</p> <p>13 specifics of the opinions that you hold.</p> <p>14 I guess just to sort of set the scope</p> <p>15 for our discussion, it's my understanding that,</p> <p>16 it's been represented to me that you intend to</p> <p>17 provide testimony solely as it relates to the</p> <p>18 issue of impact that the polymyositis would have</p> <p>19 had on Mr. Brooks had he survived the hypovolemic</p> <p>20 shock; true?</p> <p>21 A. That's correct.</p> <p>22 MR. KILBANE: To make sure we are</p> <p>23 communicating, the polymyositis and his other</p> <p>24 medical conditions.</p> <p>25 Q. You have not been asked to provide</p>	<p style="text-align: right;">7</p> <p>1 13th, indicating essentially that you have agreed</p> <p>2 to review the case of the Estate of Bessie Brooks</p> <p>3 versus The Cleveland Clinic; true?</p> <p>4 A. True.</p> <p>5 Q. Enclosed with this letter were the</p> <p>6 items which you reference in your report?</p> <p>7 A. Right.</p> <p>8 Q. I take it you didn't have any material</p> <p>9 from Mr. Kelley prior to September 13th, 2000; is</p> <p>10 that correct?</p> <p>11 A. That's correct.</p> <p>12 Q. And he indicates to you that he needs</p> <p>13 the report by the end of September, according to</p> <p>14 what he refers to as the Cuyahoga County local</p> <p>15 rules of practice; true?</p> <p>16 A. That's right.</p> <p>17 Q. I take it you weren't familiar with</p> <p>18 that procedure?</p> <p>19 A. No.</p> <p>20 Q. Now, Exhibit 2 is a copy of the report</p> <p>21 which you prepared and sent to Mr. Kelley; is</p> <p>22 that correct?</p> <p>23 A. That is correct.</p> <p>24 Q. I am going to actually have marked as</p> <p>25 Exhibit 2-A this document.</p>
<p style="text-align: right;">6</p> <p>1 opinions as to whether the doctors or nurses</p> <p>2 provided accepted standard of care in the</p> <p>3 treatment of Mr. Brooks while he was a patient</p> <p>4 following the PEG tube placement; true?</p> <p>5 A. That's true.</p> <p>6 Q. So therefore, you are not going to</p> <p>7 provide any opinions saying that the standard of</p> <p>8 care was met by any of the doctors and the nurses</p> <p>9 at Cleveland Clinic; true?</p> <p>10 A. That's correct.</p> <p>11 Q. So my questions then will</p> <p>12 intentionally be limited to talking to you about</p> <p>13 the issue of polymyositis and any co-morbid</p> <p>14 diseases that Mr. Brooks had and the opinions</p> <p>15 that you have as to issues of morbidity and</p> <p>16 mortality. Does that sound fair?</p> <p>17 A. That's correct.</p> <p>18 Q. That seems to be what you have been</p> <p>19 asked or retained to do in connection with</p> <p>20 providing opinions in this case; true?</p> <p>21 A. Yes, that's my understanding.</p> <p>22 Q. Okay. A couple of housekeeping</p> <p>23 items.</p> <p>24 Plaintiffs Exhibit 1 is a letter</p> <p>25 written to you by Mr. Kelley dated September</p>	<p style="text-align: right;">8</p> <p>1 -----</p> <p>2 (Thereupon, BALLOU Deposition</p> <p>3 Exhibit 2-A was marked for</p> <p>4 purposes of identification.)</p> <p>5 -----</p> <p>6 Q. Exhibit 2-A is, in fact, the letter</p> <p>7 which is 2, only on MetroHealth Medical Center</p> <p>8 stationery; true?</p> <p>9 A. That's right.</p> <p>10 Q. And then at the very bottom, just for</p> <p>11 identification purposes, there is a fax from</p> <p>12 Reminger & Reminger dated October 26th, 2000, and</p> <p>13 their fax number 687-1841. Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. Now, did you fax the letter to</p> <p>16 Mr. Kelley on October 26th?</p> <p>17 A. I have no idea.</p> <p>18 Q. Or might this be the date that</p> <p>19 Mr. Kelley forwarded it on to, perhaps, Mr.</p> <p>20 Mishkind, myself?</p> <p>21 A. I really have no idea.</p> <p>22 Q. Do you have any correspondence that</p> <p>23 would reflect or any documentation that would</p> <p>24 reflect the date that you sent this September</p> <p>25 29th report to Mr. Kelley?</p>

<p style="text-align: right;">9</p> <p>1 A. I don't with me at the moment. My 2 secretary probably would have that information of 3 when she sent this. The September 29th is the 4 date that I would have dictated this report, and 5 after that, I would have briefly reviewed it and 6 given it to my secretary, and she would have 7 faxed it or sent it at some point. She could 8 give you that information. 9 Q. But as to whether it was sent on the 10 29th or some date between the 29th and October 11 26th, as you sit here right now, you can't state; 12 true? 13 A. That's correct. 14 Q. Do you recall having a discussion with 15 Mr. Kelley between the time that you reviewed the 16 material on September 13th and prior to preparing 17 the September 29th letter? 18 A. I don't recall. 19 Q. By that, I take it, you may have 20 discussed with him your opinions and then 21 proceeded to prepare the report thereafter? 22 A. I might have. Usually if the letter 23 indicates, please call me with your thoughts, I 24 will do so before preparing a report. I don't 25 see such a request, so I imagine that I did not</p>	<p style="text-align: right;">11</p> <p>1 period of time; say, within a month or so of the 2 symptoms being there. Other times the diagnosis 3 may be made months, perhaps even years after the 4 patient's symptoms start; true? 5 A. That's correct. 6 Q. And the prognosis is usually better 7 for patients if the diagnosis is made early and 8 the appropriate treatment is started early as 9 opposed to a patient having the disease process 10 for months to years without being treated; true? 11 A. There are two sides to that. 12 Q. Tell me about them. 13 A. The first one is the earlier the 14 patient is treated in the course of the illness 15 from the onset of symptoms, the better the 16 prognosis. That's one side. 17 Q. Okay. 18 A. The other side deals with the rapidity 19 of the onset of the disease. Individuals who 20 have a slow insidious -- that means extended -- 21 onset tend to have a better prognosis than people 22 who have an abrupt onset. 23 Q. We can agree, can we not, that 24 Mr. Brooks, from the time that his symptoms were 25 demonstrated, apparent, to the time that the</p>
<p style="text-align: right;">10</p> <p>1 discuss it with him before preparing my report. 2 Q. As you sit here right now 3 approximately three, two and a half weeks, three 4 and a half weeks from trial, you have not seen 5 any of the testimony of any of the family 6 members; true? 7 A. That's correct, yes. 8 Q. Have you been provided with any 9 summaries of any of the testimony of the family 10 members as to Mr. Brooks' premorbid condition 11 prior to the month of May, 1998? 12 A. No, I haven't. 13 Q. As I understand it, part of the 14 process that you go through in terms of 15 evaluating the prognosis for a patient with 16 polymyositis is to look at the onset of the 17 disease process in terms of the patient's 18 condition prior to the diagnosis and how long the 19 patient had had symptomatology that was 20 eventually related to the polymyositis; true? 21 MR. KILBANE: Objection. 22 A. Yes. 23 Q. And not that it is an issue of 24 questioning the care by anyone, but sometimes 25 polymyositis is picked up in a relatively quick</p>	<p style="text-align: right;">12</p> <p>1 diagnosis was made, that the diagnosis was made 2 in a short period of time; an early diagnosis was 3 made; true? 4 A. That's correct. 5 Q. So with regard to that one aspect, 6 that helps with the prognosis factor in terms of 7 the long-term predictability; is that true? 8 A. That's correct. 9 Q. Now, the other aspect is how 10 significant the onset of those symptoms are, even 11 if the diagnosis is made early; true? 12 A. Right. 13 Q. And just give me sort of your overall 14 assessment. Recognizing that you have not talked 15 with or read any of the deposition testimony of 16 the family, but just from what you gathered in 17 the records, how would you describe from the time 18 that an early diagnosis which is good was made, 19 to the time that he started showing the 20 manifestations of the disease process, how would 21 you describe his course, if you would? 22 A. His course relative to outcome, it is 23 true that he was diagnosed early in the course, 24 which is a good thing, and treated early in the 25 course, also a good thing. It's not such a good</p>

<p>13</p> <p>1 thing that the onset was fairly abrupt in terms 2 of the severity over a period of time. So I 3 would say initial recognition was good on his 4 behalf, as well as treatment. 5 Q. Okay. 6 A. But the onset was not a good factor. 7 Q. So in terms of the kind of things that 8 you look at, the beginning of this prediction, if 9 you will, he had two out of three good aspects -- 10 early diagnosis, early treatment -- but the onset 11 was rather abrupt, so that was a strike against 12 him. So he had two out of three good things; 13 correct? 14 A. That's right. 15 MR. KILBANE: Objection. Your 16 question sort of assumes they are all equal. 17 Q. In the final analysis, they are all of 18 significant consideration, are they not? 19 A. They are all significant 20 considerations. 21 Q. Now, I sort of got ahead of myself. 22 The document that was just brought in is your CV? 23 A. That's correct. 24 Q. And we are going to mark that as 25 Exhibit 5.</p>	<p>15</p> <p>1 bibliographies, papers, that in any way relate to 2 the topic of polymyositis, okay? 3 A. Okay. 4 Q. You have sort of two questions there. 5 One to update me and two to tell me if you have 6 written anything that would be relative to 7 polymyositis. 8 (Pause.) 9 Q. Off the record, you have had a chance 10 to look at Exhibit 5. The first part of my 11 question was updates. 12 A. Yes, there is no significant update. 13 Q. The second part was have you written, 14 co-authored, provided any presentations that 15 would relate to the issue of polymyositis? 16 A. No. 17 Q. Is there anything in your 18 presentations, your background, from the 19 standpoint of authoring or lecturing that would 20 be relevant to the issue of polymyositis or any 21 of the diseases that are similar to polymyositis? 22 A. Well, as it turns out, next week I'm 23 going to give the lecture on polymyositis to the 24 second year class at the medical school, which is 25 their lecture on the subject. During the course</p>
<p>14</p> <p>1 ----- 2 (Thereupon, BALLOU Deposition 3 Exhibit 5 was marked for 4 purposes of identification.) 5 ----- 6 Q. It probably comes as no mystery, but 7 on the record, Exhibit 5 is, in fact, your CV; 8 true? 9 A. That's true. 10 Q. And it is revised as of May '99, 11 according to the page 11. What do we have to add 12 to this to bring it up to November 2000? 13 A. Probably not a lot of things, but I 14 would have to look it over. 15 Q. I would like you to take a look -- if 16 you can summarize it on the record, to just help 17 us along, do so. If you might be able to locate 18 a more current one or if it's going to take too 19 long for you to summarize the additions, I am not 20 going to have you bother doing that. I would 21 accept, perhaps, the more significant changes. 22 The other question I'm going to have 23 for you, as you look at the CV, I want you to 24 tell me whether there is anything that you have 25 written or presented by way of abstracts,</p>	<p>16</p> <p>1 of their medical school training, they get one 2 lecture on the disease, and I have lectured on 3 polymyositis and other connective tissue diseases 4 at various hospitals. 5 Q. How are you lecturing to the medical 6 students next week on polymyositis? 7 A. This will be their introductory 8 lecture, so I will be talking to them about 9 epidemiology, concepts of pathogenesis, clinical 10 manifestations, differential diagnosis will be 11 also included. 12 Q. Will you be providing them with any 13 handouts? 14 A. Sure. 15 Q. Have you prepared those handouts 16 already? 17 A. Yes, I prepared an outline for them. 18 It goes on their electronic syllabus. I am also 19 preparing a handout that I may make available as 20 hard copy, but I haven't gotten to that yet. 21 Q. What do you have that is prepared now 22 that perhaps we can get a copy of before we leave 23 today? 24 A. I have a copy of the outline of my 25 talk, which is going to be part of their</p>

<p style="text-align: right;">17</p> <p>1 electronic syllabus.</p> <p>2 Q. Could you impose upon that nice</p> <p>3 secretary of yours to get us a copy of that</p> <p>4 outline so we can continue to move along?</p> <p>5 A. It's actually on my own computer.</p> <p>6 Q. Which you only have access to?</p> <p>7 A. Yes. I am not sure she could find it.</p> <p>8 Q. How long will it take you to access</p> <p>9 that?</p> <p>10 A. About two minutes.</p> <p>11 Q. Let's go off the record and I will let</p> <p>12 you get that. I will take a look at your CV and</p> <p>13 see if there is anything I want to ask you about</p> <p>14 it, then we will move right along.</p> <p>15 (Recess had.)</p> <p>16 -----</p> <p>17 (Thereupon, BALLOU Deposition</p> <p>18 Exhibit 6 was marked for</p> <p>19 purposes of identification.)</p> <p>20 -----</p> <p>21 Q. We will mark this as Plaintiff's</p> <p>22 Exhibit 6, which is the outline that you are</p> <p>23 going to be using. We had a discussion off the</p> <p>24 record.</p> <p>25 Do you intend to cover all of what's</p>	<p style="text-align: right;">19</p> <p>1 which is a nice brief survey of major rheumatic</p> <p>2 diseases.</p> <p>3 Q. Does it have fairly reliable</p> <p>4 information on polymyositis?</p> <p>5 A. Fairly reliable.</p> <p>6 Q. Are you the sole professor for that</p> <p>7 course?</p> <p>8 A. No, no. I'm one of the teachers. I'm</p> <p>9 going to be teaching on connective tissue</p> <p>10 diseases, of which polymyositis is one.</p> <p>11 Q. Are there any other either</p> <p>12 rheumatology or neuromuscular texts that you</p> <p>13 consider to be more reliable for a general</p> <p>14 understanding of the differentiation between</p> <p>15 inflammatory myopathies and the treatment of</p> <p>16 inflammatory myopathies and the prognosis of</p> <p>17 inflammatory myopathies?</p> <p>18 A. There are a number of good texts that</p> <p>19 deal with polymyositis and other diseases. I use</p> <p>20 them all.</p> <p>21 Q. Rather than giving me the whole</p> <p>22 laundry list, tell me which one do you consider</p> <p>23 to be the best of the ones that you use, unless</p> <p>24 you want to give me the whole laundry list; but</p> <p>25 sometimes people say to me I can't name them all,</p>
<p style="text-align: right;">18</p> <p>1 in this outline with the students?</p> <p>2 A. No, not all of it.</p> <p>3 Q. What parts are you likely not to</p> <p>4 cover?</p> <p>5 A. I'm likely not to spend much time on</p> <p>6 the treatment issues, which is a level of</p> <p>7 sophistication a little greater than the</p> <p>8 students' level.</p> <p>9 Q. And I asked you off the record whether</p> <p>10 or not the outline covers prognosis, and I think</p> <p>11 you said no?</p> <p>12 A. It does not, yes.</p> <p>13 Q. Do you intend to talk about prognosis</p> <p>14 for polymyositis in this lecture?</p> <p>15 A. I probably will not.</p> <p>16 Q. The students, are they first year</p> <p>17 medical students?</p> <p>18 A. Second year.</p> <p>19 Q. Do they have a rheumatology or a</p> <p>20 neurology text that they use in connection with</p> <p>21 this course?</p> <p>22 A. They do.</p> <p>23 Q. Which text do they use?</p> <p>24 A. During their musculoskeletal rotation,</p> <p>25 they utilize the primer on rheumatic diseases,</p>	<p style="text-align: right;">20</p> <p>1 so I will make it easy for you.</p> <p>2 A. I like the Kelley text, because it's</p> <p>3 thorough, well written, and because I contributed</p> <p>4 a chapter.</p> <p>5 Q. In that order? Is it called Kelley?</p> <p>6 A. It's called, I think, Textbook of</p> <p>7 Rheumatology.</p> <p>8 Q. By Kelley?</p> <p>9 A. Kelley is the senior editor. There</p> <p>10 are four editors and I can't recall all of them</p> <p>11 offhand.</p> <p>12 There is the Oxford text. I think</p> <p>13 that's the name. I think Klippel is the main</p> <p>14 editor of that one. It's a good one, as well.</p> <p>15 The original Hollander text is a quite</p> <p>16 good text, and I think that's just called</p> <p>17 Rheumatology, as I recall.</p> <p>18 Q. Without continuing on, the ones that</p> <p>19 you named would be --</p> <p>20 A. Those three are the major ones I use.</p> <p>21 Q. And the ones that you would consider</p> <p>22 to be the most reliable for reference material on</p> <p>23 this topic?</p> <p>24 MR. KILBANE: Objection.</p> <p>25 A. In actuality, I and other physicians,</p>

<p style="text-align: right;">21</p> <p>1 we also use papers from the literature I think 2 equally to the text, because the texts are always 3 a year out of date and the papers are more 4 current, and they deal with specific issues when 5 we have specific questions. 6 Q. But of these texts which are equally 7 reliable, are these the best of the texts in 8 terms of reliability? 9 A. I think so. I think they are good 10 referral sources. 11 Q. Ones that you refer to from time to 12 time? 13 A. Yes. 14 Q. And ones which you direct future 15 medical -- future doctors to refer to for 16 reliable information? 17 A. Yes, I do. 18 Q. Now, this is the outline. Is there 19 any other material that you are planning on 20 giving them for purposes of this class? 21 A. Yes. I wrote up an illustrative 22 case. Their morning on connective tissue diseases 23 will include case discussions and I wrote an 24 illustrative case of a patient with polymyositis 25 to serve as a discussion point.</p>	<p style="text-align: right;">23</p> <p>1 polymyositis: true? 2 A. As far as is known, yes, that's true. 3 Q. And we unfortunately have the benefit 4 of an autopsy in this case to confirm that he 5 didn't have interstitial lung disease? 6 A. That's correct. 7 Q. Had he had interstitial lung disease 8 secondary to polymyositis, that would be one of 9 the poor prognosticators for this gentleman; 10 true? 11 A. Yes. 12 Q. He also did not have any type of a 13 lung carcinoma; true? 14 A. That's correct. 15 Q. That would also have been a poor 16 predictor in terms of how he would have done in 17 the long term; true? 18 A. Yes. 19 Q. He also did not have colon carcinoma; 20 true? 21 A. That's true. 22 Q. In fact, there was no evidence of any 23 malignancies that Mr. Brooks had that would 24 worsen his prognosis from his polymyositis; true? 25 A. That's true.</p>
<p style="text-align: right;">22</p> <p>1 Q. Do you have a copy of that? 2 A. Yes. I can give you a copy of that. 3 Q. Will you do that? 4 A. Fine. 5 (Recess had.) 6 ----- 7 (Thereupon, BALLOU Deposition 8 Exhibit 7 was marked for 9 purposes of identification.) 10 ----- 11 Q. Exhibit 7 is a copy of the 12 illustrative case that you are going to use for 13 purposes of second year medical school class? 14 A. That's correct. 15 Q. Is this at all based upon Lee Brooks? 16 A. No. 17 Q. Are the facts distinguishable from 18 Mr. Brooks' fact pattern? 19 A. Well, this is a case of polymyositis, 20 which I made up. It represents, I think, a 21 typical polymyositis. It's different than 22 Mr. Brooks' case in a number of ways, but similar 23 in some ways, too. 24 Q. Mr. Brooks did not ultimately have 25 interstitial lung disease secondary to the</p>	<p style="text-align: right;">24</p> <p>1 Q. So we have the facts that he didn't 2 have any underlying malignancy or any underlying 3 interstitial lung disease. Those are good 4 things? 5 A. Good things. 6 MR. KILBANE: I want to make sure I'm 7 clear. From the autopsy, does it show he does 8 not have interstitial disease or just not show 9 one way or the other? I am making sure that it's 10 clear. 11 MR. MISHKIND: It sounds like you are 12 asking him a question. 13 Q. And you have answered that there is no 14 evidence to support an argument that he had 15 interstitial lung disease at autopsy; correct? 16 A. There is no evidence to confirm that. 17 Q. So you can't take the stand and say 18 more likely than not this man had interstitial 19 lung disease; true? 20 A. I cannot say that. 21 Q. And again, going back to my original 22 question, not only do we have the records from 23 Cleveland Clinic, but then we ultimately have the 24 autopsy where tests are done to determine whether 25 or not a patient had any underlying pathology.</p>

<p style="text-align: right;">25</p> <p>1 And had there been evidence of interstitial lung 2 disease that would cause you to say that that 3 would have been a poor marker from the standpoint 4 of the man's likely long-term survival and the 5 morbidity associated with the disease; true? 6 A. It is true that that has a severe 7 implication for prognosis, the presence of 8 interstitial lung disease. 9 Q. And there is no evidence to a 10 probability that this man had evidence of 11 interstitial lung disease in this case; true? 12 A. Certainly there is not sufficient 13 evidence to document that he definitely had that 14 condition at this point. 15 Q. Well, you are not going to be able to 16 state to a reasonable degree of probability that 17 he did have it; correct? 18 A. That's right. 19 Q. Any such a statement would be pure 20 speculation? 21 A. That's correct. 22 Q. Fair enough. 23 Before I lose track of my train of 24 thought, let me just finish identifying the items 25 on here.</p>	<p style="text-align: right;">27</p> <p>1 Q. I can't help you because you wrote 2 it. I think you did, didn't you? 3 A. I wrote it. When I write a page, it 4 just means something that may have had some 5 significance to me at the time, so it's something 6 to look back on. But apparently it wasn't 7 sufficiently significant that I made any remarks. 8 Q. And then the other is page 110. Is 9 that morbidity? 10 A. Mortality. 11 Q. Mortality. And then what does it say 12 after that? 13 A. Also treatment related. 14 Q. Those are the only notes that you made 15 when you read Dr. Preston's deposition? 16 A. That's correct. 17 Q. And I think page 105, line 1 is where 18 Mr. Kelley was asking about Dr. Preston's strong 19 feelings when he read your report. Is that 20 probably why you marked that page down? If you 21 turn to page 105. 22 A. Oh, I think I marked page 105 because 23 that's the beginning of where Dr. Preston 24 addresses prognosis and my own report. So I 25 think that was the significance there. Prior to</p>
<p style="text-align: right;">26</p> <p>1 Exhibit 3, the original of which we 2 will leave with you, are notes that you made at 3 the time that you reviewed the case? 4 A. That's correct. 5 Q. And this is the extent of -- Exhibit 3 6 is the extent of the notes that you made prior to 7 preparing your September 29th, 2000 letter; true? 8 A. That's correct. 9 Q. Did you read the report from the 10 nurse? 11 A. Yes. I think maybe yesterday. 12 Q. And does that have any bearing at all 13 on the opinions that you intend to provide at the 14 trial? 15 A. No. 16 Q. So it was interesting to read, but it 17 really has no relevance to your involvement; 18 true? 19 A. Correct. 20 Q. Exhibit 4, I think, are notes that you 21 wrote after reading Dr. Preston's deposition? 22 A. That's correct. 23 Q. You have a note, page 105 -- is that 24 one or six? 25 A. I don't know what it is.</p>	<p style="text-align: right;">28</p> <p>1 that it doesn't seem like he specifically 2 addressed my report. So that's what the 3 significance of that is. 4 Q. As you read through the deposition 5 prior to getting to 105, were there any areas of 6 Dr. Preston's testimony that you took issue 7 with? 8 MR. KILBANE: Objection. 9 A. I frankly didn't pay a lot of 10 attention to it. I didn't feel that that was 11 within the area that I was inclined to look at 12 with regard to this case. 13 Q. And that's still your position as you 14 sit here right now? 15 A. That's correct. 16 Q. And no one has asked you to comment at 17 all or to provide any reaction to what's 18 contained prior to page 105; true? 19 MR. KILBANE: Objection. 20 A. That's correct. Prior to page 105, 21 the information relative to his treatment was not 22 significant to me. 23 Q. Now, we are going to talk a little bit 24 about the differences that the two of you have 25 and the specifics of Dr. Preston's disagreement,</p>

<p style="text-align: right;">29</p> <p>1 and then I am going to want you to provide me 2 with some reaction to that, okay? 3 A. Okay. 4 Q. We are not going to do that right 5 now. I'm just sort of letting you know that we 6 will be talking about that. 7 A. Okay. 8 Q. Page 110. On page 110, Dr. Preston 9 makes statements that, number one, polymyositis 10 is an autoimmune disease. That's true; correct? 11 A. Correct. 12 Q. Sometimes occurring as part of other 13 autoimmune diseases; correct? 14 A. That's correct. 15 Q. And those diseases may carry a higher 16 morbidity and mortality; correct? 17 A. Sometimes. 18 Q. Did he have other autoimmune diseases 19 aside from his polymyositis? 20 A. No, not that I can tell. 21 Q. The increased mortality of 22 polymyositis primarily has to do with the 23 association of a number of things, including 24 malignancy; true? 25 A. Yes.</p>	<p style="text-align: right;">31</p> <p>1 A. It's partially accurate. 2 Q. In your opinion, what needed to be 3 added to that to make that completely accurate? 4 A. As you can see on the remarks which I 5 wrote when I reviewed this initially, it's also 6 clear from my experience from the world 7 literature that there is a tremendous morbidity 8 and mortality associated with treatment of this 9 disease, and, in fact, probably in most series, 10 the second or third most likely cause of death is 11 infection, often related to treatment. 12 Q. Treatment being the immunosuppressant 13 therapy? 14 A. And steroids. 15 Q. Is the immunotherapy Methotrexate? 16 A. It can be. 17 Q. Imuran? 18 A. It could be. 19 Q. Are those the two immunosuppressants 20 of choice? 21 A. Yes, at present, they are. 22 Q. In conjunction with Prednisone? 23 A. Yes. 24 Q. The length of time that one is on 25 those medications varies depending upon the</p>
<p style="text-align: right;">30</p> <p>1 Q. He continues on, the association with 2 an interstitial lung disease, that also increases 3 mortality; true? 4 A. True. 5 Q. The association with other connective 6 tissue disorders; true? 7 A. That's true. 8 Q. Taken as a whole, that first paragraph 9 is an accurate statement? 10 MR. KILBANE: Objection. Howard, you 11 walked him through bit by bit all of them but 12 left off the last sentence, where he says those 13 are the primary conditions. To be fair, if you 14 are asking him the whole paragraph, we need to 15 include that also. 16 MR. MISHKIND: I meant the whole 17 sentence. Your statement is well taken then. 18 MR. KILBANE: Fair enough. 19 A. Those sentences as stated are true. 20 Q. Now, continuing on, Dr. Preston says, 21 those are the primary conditions which increase 22 the mortality of polymyositis. Do you agree with 23 that statement? 24 A. That's not completely accurate. 25 Q. Is it partially accurate?</p>	<p style="text-align: right;">32</p> <p>1 response that a patient has to treatment; true? 2 A. That's true. 3 Q. The goal is to treat a patient for a 4 period of weeks to months and to see how the 5 patient does in response to the immunosuppressant 6 therapy and the steroid therapy; true? 7 A. Yes. 8 Q. And to watch the patient? 9 A. Yes. 10 Q. And obviously to look for signs of 11 infection that may develop as the patient is 12 being treated? 13 A. Correct. 14 Q. If the patient responds well to the 15 immunosuppressant therapy, whether Methotrexate 16 or Imuran, in conjunction with Prednisone, over 17 time the dosage is tapered; true? 18 A. Often, yes. 19 Q. And then there is a maintenance dose 20 that the patient is kept on? 21 A. Most often, yes. 22 Q. And if a patient is fortunate enough 23 to have a favorable response to the 24 immunosuppressant therapy and is tapered, then 25 one starts looking in a favorable light toward</p>

<p style="text-align: right;">33</p> <p>1 the long-term prognosis for that patient; true?</p> <p>2 A. Yes.</p> <p>3 Q. In Mr. Brooks' case, we don't have the</p> <p>4 benefit of him surviving the intraabdominal</p> <p>5 hemorrhage and the multi-system organ failure to</p> <p>6 see precisely how he would have responded to the</p> <p>7 immunosuppressant therapy and the Prednisone;</p> <p>8 true?</p> <p>9 A. He didn't receive immunosuppressant</p> <p>10 therapy during the course of his life. I assume</p> <p>11 that he would have. But we certainly didn't have</p> <p>12 adequate time to observe his response to the</p> <p>13 steroids.</p> <p>14 Q. And again, that's not to criticize</p> <p>15 anyone at The Cleveland Clinic in terms of the</p> <p>16 treatment of the polymyositis, because the first</p> <p>17 line of attack is to start them on Prednisone?</p> <p>18 A. That's correct.</p> <p>19 Q. And then in conjunction with</p> <p>20 Prednisone and therapy, then in a patient that</p> <p>21 doesn't develop complications like he did, then</p> <p>22 you start them on the immunosuppressant</p> <p>23 therapies; true?</p> <p>24 A. Often that is a good choice, yes.</p> <p>25 Q. Would that likely have been what would</p>	<p style="text-align: right;">35</p> <p>1 his rehab potential as being good; correct?</p> <p>2 MR. KILBANE: Objection.</p> <p>3 A. I don't recall seeing that right</p> <p>4 offhand.</p> <p>5 Q. Well, I will represent to you that the</p> <p>6 day before his PEG tube was done, the rehab</p> <p>7 potential in the records indicate, the M.D.</p> <p>8 prognosis notes and the occupational therapy</p> <p>9 notes indicate his rehab potential was good; that</p> <p>10 they recommended subacute treatment with</p> <p>11 occupational therapy to increase independence</p> <p>12 with activities of daily living and functional</p> <p>13 mobility.</p> <p>14 If, in fact, the rehab potential, as</p> <p>15 they viewed it, was good with that plan, you</p> <p>16 wouldn't take issue with The Cleveland Clinic on</p> <p>17 that, would you?</p> <p>18 MR. KILBANE: Objection. Let's either</p> <p>19 go to the records or do it as a hypothetical.</p> <p>20 Q. I will give you that as a</p> <p>21 hypothetical, and if I am wrong with what I</p> <p>22 stated, I will fall flat on my face, but I will</p> <p>23 represent to you that that's what the record</p> <p>24 says.</p> <p>25 A. If the record indicates that he has</p>
<p style="text-align: right;">34</p> <p>1 have happened with Mr. Brooks?</p> <p>2 A. That is likely what would have</p> <p>3 happened.</p> <p>4 Q. In fact, I think the record talked</p> <p>5 about him being --</p> <p>6 (discussion off the record.)</p> <p>7 Q. The records even would reflect that he</p> <p>8 was going to be transferred the following day to</p> <p>9 a subacute facility for rehab?</p> <p>10 A. Yes.</p> <p>11 Q. And that would have been an</p> <p>12 appropriate thing to do?</p> <p>13 A. That would have been appropriate to</p> <p>14 do.</p> <p>15 Q. And then he would have been treated</p> <p>16 with the steroids and the immunosuppressant</p> <p>17 therapy for a period of four to six weeks with</p> <p>18 tapering thereafter; true?</p> <p>19 A. Probably something of that nature,</p> <p>20 yes.</p> <p>21 Q. In fact, that's what the plan was</p> <p>22 before he experienced this tragic outcome; true?</p> <p>23 A. True.</p> <p>24 Q. And you would agree with the doctors</p> <p>25 at The Cleveland Clinic when they talked about</p>	<p style="text-align: right;">36</p> <p>1 good rehab potential, I think that that's</p> <p>2 appropriate for them to so state. Can I leave it</p> <p>3 at that?</p> <p>4 Q. Well, do you or do you not disagree</p> <p>5 with The Cleveland Clinic in terms of the</p> <p>6 statement that they made, before there is any</p> <p>7 litigation and while they are looking at this</p> <p>8 patient, that he had good rehab potential?</p> <p>9 MR. KILBANE: Objection. Asked and</p> <p>10 answered. Go ahead.</p> <p>11 A. My point here is that everybody with</p> <p>12 this disease has rehab potential. And everybody</p> <p>13 deserves rehabilitation.</p> <p>14 I am not clear about "good" here. I</p> <p>15 have seen a number of patients with this</p> <p>16 disease. I personally am not certain that I</p> <p>17 would have said good rehabilitation. Certainly</p> <p>18 rehabilitation potential and certainly he needed</p> <p>19 this treatment, but they may -- I didn't see him</p> <p>20 and they saw him. Maybe they somehow had a</p> <p>21 better feel for it than I got from reading the</p> <p>22 case.</p> <p>23 Q. Reading the case as an expert witness</p> <p>24 that's coming in to provide opinions in this case</p> <p>25 as an expert retained by The Cleveland Clinic,</p>

<p style="text-align: right;">37</p> <p>1 what would you have indicated as his rehab 2 potential? 3 A. Fair. 4 Q. Several days before his PEG tube was 5 placed, there is a notation in the records -- I 6 ask you to assume hypothetically, just to save 7 some time --that Mr. Brooks was told that he 8 would be going to a subacute facility first for 9 physical therapy before he could then be 10 discharged back to his home. 11 Number one, assuming that's the 12 information that they gave to him, would that 13 likely be an accurate statement of anticipated 14 treatment for him? 15 MR. KILBANE: Objection. 16 A. That would be an accurate statement of 17 an anticipated treatment, yes. 18 Q. Assuming that the patient survived the 19 intraabdominal hemorrhage and this catastrophic 20 death that he experienced and went to rehab, can 21 we agree that he would have been a candidate for 22 rehabilitation at the subacute facility with 23 subsequent discharge to his home? 24 MR. KILBANE: Objection. Go ahead. 25 A. I presume that would be the plan, yes.</p>	<p style="text-align: right;">39</p> <p>1 facility and then a long-term facility for the 2 rest of his life; true? 3 MR. KILBANE: Objection. 4 A. I cannot conclude that. 5 Q. We can all agree that he needed 6 treatment for the polymyositis and rehab. What 7 you are agreeing with me about is that the 8 future, as to where he would live and what type 9 of independence he would have, you are not going 10 to be able to give an opinion one way or the 11 other on that; true? 12 MR. KILBANE: Objection. 13 A. One can only frame this in terms of 14 probabilities. 15 Q. And can you state to a probability 16 what type of independence he likely would have 17 had? 18 MR. KILBANE: Feel free to refer to 19 your report or any of the records. 20 A. My estimate is that he would not have 21 reached full functional recovery perhaps ever. 22 My estimate is that he would probably have, with 23 good rehabilitation, immunosuppressant therapy, 24 that he probably would have had about a 50-50 25 chance of independent mobility. That means</p>
<p style="text-align: right;">38</p> <p>1 Q. And to a probability, with treatment, 2 can we agree that he likely would have gone to 3 rehab for a period of time and then likely have 4 been discharged to his home? 5 A. I feel certain that he would have gone 6 to rehabilitation for a certain period of time. 7 I'm not so certain that he would have been 8 discharged home. I think that clearly would have 9 depended upon his response to therapy and his 10 condition when he had reached optimal 11 rehabilitation. 12 For example, I see patients who failed 13 to have adequate success with rehabilitation in 14 whom, for whatever reason, it is felt that an 15 extended care facility is more appropriate. 16 Q. But you can't state to a probability 17 that Mr. Brooks would not have responded to 18 immunosuppressant therapy and have been able to 19 be discharged? 20 A. There clearly was not enough time to 21 tell this. 22 Q. So when you take the stand and 23 testify, you are not going to be able to state 24 that it's my opinion to a reasonable degree of 25 probability that he would have been in a rehab</p>	<p style="text-align: right;">40</p> <p>1 ambulation with perhaps assistance, but 2 independently, say with a walker or cane or 3 something like that. 4 Q. Those are your opinions to a 5 probability? 6 A. That's my opinion. 7 Q. Thankyou. 8 I am going to redirect your focus now 9 away from polymyositis. Parenthetically though, 10 I am going to come back to polymyositis before we 11 conclude. 12 A. That's fine. 13 Q. I am going to talk to you about your 14 medical/legal experience. 15 A. Okay. 16 Q. Have you ever served as an expert 17 witness in a medical negligence case before? 18 A. Once or twice. 19 Q. How long ago would that be? 20 A. The most recent was within the past 21 two months. 22 Q. Now, in this case, you are not 23 providing opinions on standard of care; i.e., 24 that The Cleveland Clinic met accepted standards 25 of care. You are testifying on the issue of</p>

<p style="text-align: right;">41</p> <p>1 proximate cause, the issue of disability had he 2 not succumb to this situation. 3 In the other case two months ago, was 4 your role different? 5 A. Yes. It was relative to standard of 6 care. 7 Q. Was this in a rheumatological 8 condition? 9 A. Yes. 10 Q. What was the nature of that condition? 11 A. Rheumatoid arthritis. 12 Q. As to whether rheumatoid arthritis was 13 treated properly? 14 A. That was part of the issue, yes. 15 Q. Was there some other diagnosis arrived 16 at? 17 A. Yes. The person had tuberculosis. 18 Q. Probably had night sweats? 19 A. Yes. 20 Q. Is that case still pending? 21 A. I don't believe so. I think it was 22 concluded. 23 Q. Was your deposition taken? 24 A. Yes. 25 Q. Were you appearing as the expert for</p>	<p style="text-align: right;">43</p> <p>1 A. I don't remember what he looked like. 2 (Discussion off the record.) 3 Q. Your deposition was taken by the 4 plaintiff's attorney in that case? 5 A. Yes. 6 Q. And who was the plaintiff's attorney; 7 do you recall that? 8 A. I forget. 9 Q. The depo was taken two months ago. 10 And to your knowledge, the case has gone away? 11 A. I think the case was settled, I think. 12 Q. Was the lawyer, by chance, Bill 13 Carlin? 14 A. That sounds like it could be it. 15 Q. Sort of a heavy set fellow? 16 A. Yeah, I believe it was. 17 Q. Aside from that situation, any other 18 cases that -- 19 A. Not in recent memory. Maybe one or 20 two in the past. 21 Q. Had you ever testified in a deposition 22 in a med/mal case before this one a couple months 23 ago? 24 A. Once I testified in a deposition in a 25 medical malpractice case where the patient was my</p>
<p style="text-align: right;">42</p> <p>1 the patient, the plaintiff, or an expert for the 2 doctor or hospital that was implicated? 3 A. I was appearing on behalf of the 4 defense. 5 Q. And who was the doctor or the 6 hospital, or both? 7 A. The hospital was University Hospital, 8 and the doctor was Dr. Van Warren. 9 Q. And who was the lawyer that you were 10 working with? 11 A. The firm was Reminger. 12 Q. That would be Reminger & Reminger? 13 A. Reminger & Reminger. 14 Q. I have heard of them. 15 And who would the lawyer be that you 16 were working with in that case? 17 A. The lawyer I was working with? 18 Q. From the Reminger firm. 19 A. From Reminger? I just saw his name. 20 Conway. 21 Q. Tom Conway? 22 A. That's it. 23 Q. A red head, tall, thin? 24 A. I don't remember what he looked like. 25 Q. Better looking than Kilbane?</p>	<p style="text-align: right;">44</p> <p>1 patient and I wasn't on either side. I was asked 2 to testify about my patient's condition. 3 Q. You were the treating physician? 4 A. I was the treating physician. So I 5 guess they just wanted information from me about 6 my patient. 7 Q. So the time that this lawyer took your 8 deposition in the University Hospital case, would 9 that have been the first time where you were 10 retained specifically to provide expert opinions 11 in a standard of care context? 12 A. Where I actually was deposed, yes. I 13 have been in other cases where I wasn't deposed. 14 Q. And that would be one or two other 15 occasions? 16 A. One or two. 17 Q. And that would be where you wrote 18 reports perhaps to the attorney but never got to 19 the deposition or trial stage? 20 A. Exactly. 21 Q. I take it you have never marched into 22 the courtroom and testified, taken the stand and 23 testified in a medical malpractice case? 24 A. That's correct. 25 Q. The other one or two cases, roughly</p>

<p>45</p> <p>1 speaking, that you reviewed and wrote reports on, 2 would those have been at the request of attorneys 3 representing the physician or hospital or the 4 attorney representing the patient? 5 A. Both. 6 Q. One of each? 7 A. Yes, one of each, I think. 8 Q. Fair enough. 9 Have you ever had the misfortune of 10 being named as a defendant in a medical 11 negligence case? 12 MR. KILBANE: Objection. You can 13 answer. 14 A. I think so. 15 Q. Why do you say it in that manner? 16 That's something normally known if you are, 17 A. About 20 years ago, I was named as a 18 defendant in a suit, because I had given a 19 lecture. And so I had to do a deposition and 20 then I was dismissed. 21 Q. Other than that situation, you 22 fortunately have not been named? 23 A. That's correct. 24 Q. Fair enough. 25 Are you currently reviewing any other</p>	<p>46</p> <p>1 matters for the Reminger & Reminger firm? 2 A. No. 3 Q. And when Mr. Kelley contacted you, I 4 take it, it was because of having received your 5 name from Mr. Conway? 6 MR. KILBANE: Objection. 7 A. I really have no idea. 8 Q. Have you ever provided your name to 9 any of the services that make expert witnesses 10 available in medical negligence cases? 11 A. I don't believe so. 12 Q. Has the department of rheumatology 13 here at Metro published any literature dealing 14 with the issue of morbidity and mortality 15 associated with polymyositis? 16 A. Not that I'm aware. 17 Q. Are you aware of any studies or 18 literature from the Mayo Clinic that have to do 19 with the issue of morbidity and mortality 20 associated with polymyositis? 21 A. Oh, years ago there was a very good 22 paper published by a bunch from the Mayo Clinic 23 on the treatment of polymyositis using Imuran. I 24 don't recall whether they addressed the issues of 25 morbidity -- well, they did address the issues of</p>	<p>47</p> <p>1 morbidity, absolutely they did. I don't know 2 about mortality. 3 It was a nice study focusing on the 4 benefits of Imuran to the current therapy, which 5 at that time was mostly Prednisone. 6 Q. How long ago was that article written? 7 A. That was probably in about 1980 to 8 '82, somewhere around that range. 9 Q. Have things changed with regard to the 10 treatment and the issue of morbidity and 11 mortality in polymyositis over the last 20 years? 12 A. Yes. More people are using certainly 13 immunosuppressants along with steroids. There 14 are recent trends to use Methotrexate rather than 15 Imuran. And even recent studies from Pittsburgh 16 and other areas have suggested that certain other 17 agents such as Cyclosporine A could also be used 18 for refractory cases. 19 Q. And certainly you are not going to be 20 able to state to a probability that Mr. Brooks 21 had a refractory case of polymyositis; true? 22 A. That's true. 23 Q. The Mayo Clinic study then in terms of 24 the treatment modalities wouldn't really be up to 25 speed with regard to the current thought process</p>	<p>48</p> <p>1 as it relates to treatment modalities for the 2 year 2000; correct? 3 A. There is more recent data that we use, 4 yes. 5 Q. And even more recent than 1998? 6 A. Yes. 7 Q. I am talking about current. This was 8 a 1998 situation. So the analysis and the 9 treatment modalities would not have been guided 10 by the study from 1980 at the Mayo Clinic; true? 11 A. That's right. 12 Q. What about any studies or literature 13 from Johns Hopkins that you are aware of dealing 14 with the issue of morbidity and mortality 15 associated with polymyositis? 16 A. Mark Hochburg has published a nice 17 study of morbidity and mortality in 1986. It was 18 a nice study that addressed this issue. 19 Q. What was the name of that doctor? 20 A. Mark Hochburg. 21 Q. How does he spell his last name? 22 A. H-O-C-H-B-U-R-G. 23 Q. Have you reviewed his article at all 24 in connection with the preparation of the opinion 25 letter that you have prepared?</p>
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<p style="text-align: right;">49</p> <p>1 A. No, not recently. I am familiar with 2 the article, but I haven't reviewed it recently. 3 Q. Do you consider it to be 4 authoritative? 5 MR. KILBANE: Objection. 6 A. Well, there is really quite a few 7 articles I think in this fashion. I use a vast 8 number of articles. I mean, I still like the 9 Mayo Clinic article, I like Hochburg, the famous 10 Peter and Bolan article. I like more recent 11 articles from Targoff in Oklahoma and Kagan at 12 HSS. So there is really quite a few papers that 13 I read about this. I read about this, as do most 14 rheumatologists quite often. 15 Q. In arriving at the opinions that you 16 expressed in this report -- I am trying to 17 shortcut it because I realize you have patients 18 -- did you look to any of the medical literature 19 in citing any of the statistics that you have 20 relied on for purposes of this letter? 21 A. The statistics that I cited, I'm aware 22 of, I was already aware of from the literature. 23 I didn't cite that many statistics. I think I 24 only cited a couple of them. But those are 25 things known to me from just my review of the</p>	<p style="text-align: right;">51</p> <p>1 65-year-old, Mr. Brooks or any 65-year-old. 2 Q. Let me ask you this. Can you cite me 3 any literature that would address the issue of 4 the morbidity -- I'm sorry, the survival with 5 reasonable and prudent treatment for polymyositis 6 for a gentleman that is 65 years of age, that has 7 Mr. Brooks' co-morbid conditions that does not 8 have any associated malignancy? 9 A. To my knowledge, that data does not 10 exist in the literature. 11 Q. As far as the survival of 80 percent 12 at five years in adult patients, would you agree 13 that those studies deal with patients of all 14 adult ages? 15 A. Yes. 16 Q. And in fact, if I'm referring to the 17 same studies that you are -- maybe I'm not -- but 18 those studies include patients older than 65, as 19 well as younger than 65? 20 A. All adult patients. 21 Q. And the conclusion was 80 percent, 22 five year survival in those studies, but it 23 doesn't break it down to a 30 percent for people 24 at 65, a 90 percent for people at 55; correct? 25 A. That's my recollection, yes.</p>
<p style="text-align: right;">50</p> <p>1 literature previously. 2 Let's see, 80 percent, five year 3 survival represents -- there is a range certainly 4 and there are other survival figures reported -- 5 but this is one that I happen to remember. 6 Q. Let's deal with one at a time on that. 7 I don't mean to interrupt you. I am going to let 8 you continue to answer that, but I think maybe to 9 help us move things along, on that point, you 10 state the 80 percent survival without associated 11 malignancy; correct? 12 A. That's right. 13 Q. And that would be where Mr. Brooks 14 would fall; correct? 15 MR. KILBANE: Objection. 16 A. Not necessarily. This is an 80 17 percent, five year survival in all adult 18 patients, including patients age 55. That would 19 not apply to an individual age 65. 20 Q. Well, this doesn't talk about -- 21 A. This is an 80 percent, five year 22 survival of all adult patients, which the mean 23 age is probably mid 40s. 24 Q. Okay. 25 A. So this statistic would not apply to a</p>	<p style="text-align: right;">52</p> <p>1 Q. So the best scientific evidence that's 2 available right now is what you have stated in 3 terms of 80 percent, five year survival in adult 4 patients without associated malignancy; correct? 5 A. Yeah, that would be a reasonable 6 projection, yes. 7 Q. Are you aware of any studies that have 8 projected out beyond five years in terms of the 9 degree of survival on patients that have 10 polymyositis with an onset at the age of 65? 11 A. There is a study recently that 12 addressed prognosis in older individuals. There 13 have been several such studies. I don't know if 14 they actually looked at Kaplan Myer statistics, 15 which is survival rates as you see here in older 16 individuals. But studies that have looked at 17 age, always associate age as a poor prognostic 18 factor; that is, with increasing age, survival 19 and, in fact, morbidity are reduced. 20 Q. Can you tell me in this case if 21 Mr. Brooks had not encountered this disease of 22 polymyositis with his underlying coronary artery 23 disease what his life expectancy would have been? 24 A. I can hazard a guess. 25 Q. If it's a guess, I don't want it. If</p>

<p style="text-align: right;">53</p> <p>1 you can provide me with an opinion to a 2 reasonable degree of probability what his life 3 expectancy would be, then I do want that. 4 A. No, I think you could find such 5 information from tables, from national tables of 6 individuals with coronary artery disease, black 7 males age 65, I think you can find expected 8 survival rates and I won't quote you one. 9 Q. Well, you are aware of the United 10 States life tables, are you not? 11 A. Yes. 12 Q. And the United States life table 13 address a 65-year-old black male; correct? 14 A. Correct. 15 Q. And that deals with all comers? 16 A. Yes. 17 Q. So that takes an average of certain 18 people that will live beyond those figures and 19 certain people that are going to die earlier? 20 A. That's correct. 21 Q. If I told you the life expectancy for 22 a 65-year-old man, according to the United States 23 life tables, is 15 years, all comers, some going 24 to live longer, some live less, and I represent 25 that to you to be what the United States life</p>	<p style="text-align: right;">55</p> <p>1 focusing on polymyositis, if he had a very good 2 response to therapy and became ambulatory, his 3 survival would still have been reduced, just on 4 the basis of having polymyositis alone. And my 5 estimate is that it would be reduced, oh, if you 6 said 15 years survival, say, for example, 10 to 7 12 years, 10 to 12 years total. 8 Q. So his life expectancy would be 10 to 9 12 as opposed to that theoretical 15? 10 A. Right. 11 Q. So roughly a ten to 20 percent 12 reduction in life expectancy? 13 A. Right. 14 Q. The overall prognosis being worse in 15 African-Americans than Caucasians, do you have 16 any studies that support that proposition? 17 A. It has been mentioned in the 18 literature. 19 Q. What literature? 20 A. The literature focused on the 21 polymyositis in a number of papers and a number 22 of reports have suggested that. 23 Q. Can you cite me to any specific? 24 A. Not without going back and looking at 25 my files.</p>
<p style="text-align: right;">54</p> <p>1 tables provide, would you have any basis to 2 dispute that? 3 A. No, not at all. 4 Q. Would you expect that with 5 polymyositis-- again, not knowing how his 6 response was going to be because he hadn't had 7 the immunosuppressant therapy, but assuming he 8 had a good course to the Methotrexate and/or the 9 Imuran and that he was able to be ambulatory -- 10 we know that he had the PEG tube, so he was no 11 longer at risk for aspiration pneumonias; 12 correct? 13 A. Uh-huh. 14 Q. That's a yes? 15 A. That's theoretically correct, yes. 16 Q. So if he had had a good response to 17 the immunosuppressant therapy and/or the Imuran 18 and became ambulatory, can you state to what 19 extent his life expectancy would have been 20 reduced from the United States life table 21 expectations? 22 MR. KILBANE: Objection to a 23 hypothetical. Go ahead and answer. 24 A. Yes. Ignoring other co-morbid 25 diseases, such as atherosclerosis and just</p>	<p style="text-align: right;">56</p> <p>1 Q. Do you have files that deal with -- 2 A. Polymyositis? 3 Q. Specifically that would address the 4 issue of Caucasian versus African-American 5 survival? 6 A. I have a large file of papers on 7 polymyositis and some of them do address this 8 issue. 9 Q. I would like to see those if they are 10 the ones that you are relying on for that 11 proposition. 12 MR. KILBANE: Objection. 13 Q. Will you look for those and make those 14 available? 15 A. If you would like me to, I can show 16 you such statements in the literature. 17 Q. Are you aware of whether or not that 18 is more of a component of the quality of medical 19 care that historically has been provided to 20 African-Americans versus Caucasians? 21 A. The answer to that is not clear. If 22 we look at a related condition called lupus where 23 there is clearly a reduced survival in 24 African-Americans with this disease, it is 25 thought that socioeconomic factors and access to</p>

<p style="text-align: right;">57</p> <p>1 care could be part of the explanation, but 2 probably not the entire explanation, and there 3 are a reasonable number of individuals, including 4 myself, who think that there are potentially 5 genetic factors that also play a role. 6 Q. But you certainly wouldn't rule out 7 that our socioeconomic setup is such that at 8 least a factor in why African-Americans do worse 9 than Caucasians has been access to medical care? 10 A. I think that's one factor, yes. 11 Q. It may not necessarily be an 12 overwhelming factor? 13 A. It's one factor. 14 Q. When one talks about African-Americans 15 having a poorer prognosis than Caucasians with 16 polymyositis, you certainly have to admit that a 17 factor that has to be taken into account by 18 people listening to that is access to medical 19 care hasn't always been the same for black 20 Americans as it has been for white Americans? 21 A. I'm sure that's true. 22 Q. Older age is known to be associated 23 with worse prognosis and you have greater than 24 55. 25 A. Yes.</p>	<p style="text-align: right;">59</p> <p>1 opinions on morbidity and mortality, there are a 2 number of different studies, none of which 3 predominate such that you can say that Mr. Brooks 4 had a lower survival rate simply because he was 5 over age 55; true? 6 MR. KILBANE: Objection. 7 A. I am not sure I understand that 8 question. 9 Q. Fair enough. You indicate that older 10 patients are known to have a worse prognosis of 11 -- let me put it to you this way. Can you tell 12 me how worse off he would have been in terms of 13 his prognosis in this case, simply because he was 14 65 years of age? 15 A. Can I quantify how much worse? 16 Q. Yes. 17 A. I think that that is probably not 18 possible to do. 19 Q. Fair enough. 20 The pharyngeal dysfunction which 21 occurs in ten to 15 percent of the cases, that's 22 associated with substantially worse prognosis; 23 true? 24 A. That's correct. 25 Q. Fortunately, he had an early diagnosis</p>
<p style="text-align: right;">58</p> <p>1 Q. Can you cite me to any literature as 2 it relates to polymyositis that would support a 3 55 age cutoff, if you will, where patients above 4 55, Mr. Brooks, being ten years older than that, 5 but a patient above 55 has a poorer prognosis 6 from polymyositis than a patient under 55? 7 A. Yes, I have seen that in the 8 literature. 9 Q. Have you also seen articles that 10 indicate patients 65 have the same kind of 11 prognosis as patients the age of 55? 12 A. See, the literature doesn't make -- 13 different studies make different age cutoffs. I 14 have seen it said that individuals 65 and older 15 do worse. I have seen it reported that 16 individuals 55 and older do worse. So we deal 17 with a whole body of literature of which there 18 are multiple age cutoffs. 19 Suffice it to say, that virtually all 20 studies indicate age as being a substantial risk 21 factor as you get older throughout life, 22 probably. I don't know that we could definitely 23 say there is one cutoff age where people are 24 clearly going to do worse. 25 Q. So for purposes of understanding the</p>	<p style="text-align: right;">60</p> <p>1 of his polymyositis; true? 2 A. True. 3 Q. And he had an attempt to avoid further 4 esophageal dysfunction by putting the PEG tube 5 in; correct? 6 MR. KILBANE: Objection. 7 A. To avoid complications of the 8 esophageal dysfunction. 9 Q. And had the PEG tube been successful 10 and he didn't develop an intraabdominal 11 hemorrhage and then die following that, the 12 issues of esophageal or pharyngeal dysfunction 13 would not have been a factor in Mr. Brooks' case; 14 true? 15 MR. KILBANE: Objection. 16 A. Not entirely. The pharyngeal 17 dysfunction as a sign of poor prognosis is 18 related to two factors: One is the complications 19 of that dysfunction, aspiration, et cetera, which 20 clearly would be corrected by placement of the 21 PEG tube. 22 The other aspect is the significance 23 of pharyngeal dysfunction in terms of the disease 24 severity. And this is clearly noted in the 25 literature, and it's my experience, as well,</p>

<p>61</p> <p>1 individuals who have disease severe enough to 2 cause pharyngeal dysfunction almost always have 3 the most severe muscle involvement, generally. 4 So it portends a poor prognosis just from it's an 5 indicator of the disease severity, which is 6 substantial.</p> <p>7 The ten to 15 percent of individuals 8 with pharyngeal dysfunction are also those who 9 have the most severe disease. This is not just 10 the literature, this is my experience, as well.</p> <p>11 Q. But, doctor, wouldn't you agree with 12 me that in the literature that the patients that 13 have the pharyngeal dysfunction which have a much 14 more substantial worse prognosis are more often 15 than not the patients that have had a long course 16 of symptoms before they are treated and diagnosed 17 with polymyositis?</p> <p>18 A. Not necessarily. Some are. But I 19 have seen and it is well described, some 20 individuals, unfortunately with a poor prognosis, 21 do present rapidly and dramatically with profound 22 weakness within weeks, including pharyngeal 23 dysfunction. And the literature suggests, and I 24 agree with that, that these individuals have the 25 severest disease and the worst prognosis.</p>	<p>63</p> <p>1 dysfunction for long periods of time without 2 seeking medical care. It's an awful situation if 3 you see it clinically.</p> <p>4 Q. But he is in the hospital at The 5 Cleveland Clinic when these symptoms develop that 6 started portending the existing pharyngeal 7 dysfunction; true?</p> <p>8 MR. KILBANE: Objection.</p> <p>9 A. Right.</p> <p>10 Q. He is treated early for the pharyngeal 11 dysfunction at the Cleveland Clinic; true?</p> <p>12 A. That's correct.</p> <p>13 Q. That would be a good prognostic 14 indicator as it would relate to the association?</p> <p>15 A. It's a good prognostic indicator 16 relative to preventing complications such as 17 aspiration, yes.</p> <p>18 Q. Severe muscle weakness at presentation 19 is a very poor prognostic factor?</p> <p>20 A. That's right.</p> <p>21 Q. However, you also recognize that 22 patients have a variable course in terms of the 23 response to Methotrexate and to Imuran and even 24 patients with severe muscle weakness frequently 25 become ambulatory and independent; true?</p>
<p>62</p> <p>1 Q. But again, you wouldn't disagree with 2 me when I say that there are studies that show 3 that patients with pharyngeal dysfunction that 4 have worse prognosis are also frequently those 5 who have had a long course of symptoms before 6 they are diagnosed and treated for the 7 polymyositis?</p> <p>8 MR. KILBANE: Objection.</p> <p>9 A. I'm not sure of the use of the term 10 frequently. Some have.</p> <p>11 Q. And the poor prognosis associated with 12 the pharyngeal dysfunction in a lot or in a large 13 majority of those patients that have a poor 14 prognosis, they have already experienced 15 aspiration and complications from the pharyngeal 16 dysfunction; correct?</p> <p>17 MR. KILBANE: Objection.</p> <p>18 A. I'm not certain that's correct. Most 19 individuals in my experience with substantial 20 pharyngeal dysfunction seek medical care quite 21 quickly. It's a tremendously dysfunctional 22 complication, manifestation.</p> <p>23 These patients can't control their own 24 secretions. It's rare in my experience for 25 individuals to have significant pharyngeal</p>	<p>64</p> <p>1 A. I am not sure about frequently. There 2 is certain a gradation of muscle weakness. I see 3 many patients who present and are diagnosed and 4 are ambulatory at the time they are diagnosed 5 with mild dysfunction. It is in my experience 6 uncommon to see someone with muscle weakness so 7 profound that they have truncal weakness, unable 8 to support themselves in bed. That's profound 9 weakness. Such cases are quite uncommon.</p> <p>10 I think in patients with this severity 11 of weakness -- I have seen maybe two -- and 12 really the severity of this weakness is 13 substantial. It does not preclude improvement, 14 but I have to temper my statements with I think 15 it would require prolonged treatment, a 16 tremendous Tour de Force of rehabilitation and I 17 doubt that the outcome would be entirely 18 satisfactory. This is profound weakness.</p> <p>19 Q. And you have said to me, taking 20 everything into account, that he had at best a 21 50-50 chance of becoming ambulatory?</p> <p>22 A. Correct.</p> <p>23 Q. Taking all factors into account?</p> <p>24 A. Taking solely the extent of his 25 weakness and the rapidity of his onset.</p>

<p style="text-align: right;">65</p> <p>1 Q. Because we didn't have the benefit of, 2 the opportunity to see how he responded to the 3 immunosuppressant therapy? 4 A. We did not, but my guess is he would 5 not have any better than a 50-50 chance of being 6 ambulatory. 7 Q. Obviously you would be optimistic and 8 be encouraging the patient and the family that he 9 would be able to be independent in the future; 10 true? 11 A. I would hope so. 12 Q. And you want to be optimistic and 13 encouraging the family because you know that with 14 treatment and with tender loving care from the 15 family that that 50-50 shot of becoming 16 ambulatory could become better; correct? 17 MR. KILBANE: Objection. 18 A. Partially. It is good to be 19 optimistic. It is also good to tell the family 20 the truth. I think it's important that the 21 family and the patient realize the challenges 22 ahead. 23 I have no problem with telling a 24 patient or their family that this is a serious, 25 serious problem, and without tremendous effort on</p>	<p style="text-align: right;">67</p> <p>1 A. Yes. 2 Q. That's the steroid? 3 A. Right. 4 Q. And he then would have required -- we 5 have talked about this -- the immunosuppressant 6 therapy over months? 7 A. This is an individual that would have 8 required that, yes. 9 Q. Could you tell me with successful 10 treatment how long he would have needed the 11 immunosuppressant therapy before being tapered 12 off completely? 13 A. I think it's unlikely that he would 14 have been tapered off any immunosuppressant 15 completely. 16 Q. He would have been tapered; true? 17 A. He would have been tapered from the 18 steroids. I doubt that he would have been taken 19 off of the immunosuppressant. 20 Q. Why? 21 A. Because many patients have 22 recurrences, at least a third. Most of my 23 patients with polymyositis are on 24 immunosuppressants for a long time. I currently 25 have six patients with polymyositis, all but one</p>
<p style="text-align: right;">66</p> <p>1 everybody's part, the outcome could be worse. I 2 want people to know up front exactly what I think 3 is going on. I want them to accept this as 4 challenging, because most of the rehabilitation 5 occurs on the part of the afflicted individual 6 and it's hard. 7 Q. So then you think that The Cleveland 8 Clinic, when they say that the rehab potential 9 was good, you, Dr. Ballou, think that maybe they 10 are painting the glass half full rather than half 11 empty? 12 A. That particular comment. That single 13 comment you mentioned, whoever made it, yes, I 14 think. 15 Q. Now, when you find out that a patient 16 has polymyositis as opposed to something like Lou 17 Gehrig's disease, you are happy, are you not? 18 A. I don't treat Lou Gehrig's disease, 19 but certainly if I had to have one or the other, 20 I would rather have polymyositis. 21 Q. Because polymyositis, while it's not 22 curable, it is treatable? 23 A. It's treatable. 24 Q. Would you agree that Mr. Brooks was 25 initially treated with Solu-Medrol?</p>	<p style="text-align: right;">68</p> <p>1 still on immunosuppressants, and this is years 2 following diagnosis. 3 Q. What is the longest term patient that 4 you have had that has polymyositis? 5 A. Well, that I am currently following, I 6 am following a fellow who has had it for 15 years 7 and he is still on Methotrexate. 8 Q. How old is that fellow? 9 A. Now, he is probably about 45. 10 Q. What is the oldest patient that you 11 have that has polymyositis? 12 A. I have a woman who is in her probably 13 early 70s with polymyositis. 14 Q. Did you treat her from the onset? 15 A. Yes. 16 Q. Is she ambulatory? 17 A. Yes. 18 Q. Was she ambulatory at the time of 19 onset? 20 A. She was always ambulatory. 21 Q. What were her symptoms? 22 A. Weakness in her arms and legs; some 23 difficulty getting out of a chair; some 24 difficulty getting in and out of the car; feeling 25 of weakness when she was doing her hair.</p>

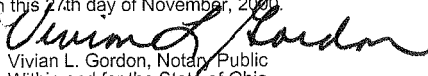
<p style="text-align: right;">69</p> <p>1 Q. What about any pharyngeal dysfunction?</p> <p>2 A. None.</p> <p>3 Q. Do you have any patients that had</p> <p>4 pharyngeal dysfunction?</p> <p>5 A. Yes. I have over the years, yes.</p> <p>6 Q. You have, okay. How long did you</p> <p>7 treat those -- do you still have any patients</p> <p>8 that have pharyngeal dysfunction?</p> <p>9 A. The one man who I have treated with</p> <p>10 Methotrexate now for 15 years, he had pharyngeal</p> <p>11 dysfunction that has now resolved.</p> <p>12 Q. Did they PEG him?</p> <p>13 A. He did not need a PEG.</p> <p>14 Q. A patient that has pharyngeal</p> <p>15 dysfunction that has a PEG tube that is treated</p> <p>16 with immunosuppressant therapy, are they lifetime</p> <p>17 committed to the PEG tube?</p> <p>18 A. I don't know for sure. I have only</p> <p>19 had one patient who was treated with a PEG tube</p> <p>20 for pharyngeal dysfunction. I don't know if it's</p> <p>21 lifetime.</p> <p>22 Q. A patient that you had that was</p> <p>23 treated with the PEG tube, does the patient still</p> <p>24 have the PEG tube or was it reversed?</p> <p>25 A. He died.</p>	<p style="text-align: right;">71</p> <p>1 while he did have ischemic cardiovascular disease</p> <p>2 and had high cholesterol, his cardiac status was</p> <p>3 stable?</p> <p>4 A. I'm not certain that we can actually</p> <p>5 state that.</p> <p>6 Q. Are you able to state that he had</p> <p>7 significant ongoing cardiac abnormalities that</p> <p>8 would cause him to be unstable from a cardiac</p> <p>9 standpoint?</p> <p>10 A. Well, the autopsy reflected that he</p> <p>11 had cardiomegaly and hypertrophy. I'm not a</p> <p>12 cardiologist. But those are not good things to</p> <p>13 have. I think they reflect the presence of</p> <p>14 significant cardiac disease, per se. How</p> <p>15 significant, you would have to ask a</p> <p>16 cardiologist.</p> <p>17 Q. You are certainly not going to be in a</p> <p>18 position to testify that a cardiac condition in</p> <p>19 and of itself was likely to cause this</p> <p>20 gentleman's death in the foreseeable future, are</p> <p>21 you?</p> <p>22 A. What I can say is the fact that he had</p> <p>23 significant cardiovascular disease would have</p> <p>24 adversely influenced his mortality as compared</p> <p>25 with a 65-year-old African-American male who did</p>
<p style="text-align: right;">70</p> <p>1 Q. What did he die of?</p> <p>2 A. He had a cardiac death related to his</p> <p>3 myositis.</p> <p>4 Q. Was there an autopsy done?</p> <p>5 A. I don't recall. This was probably 12,</p> <p>6 15 years ago.</p> <p>7 Q. How old was that patient?</p> <p>8 A. He was about 48.</p> <p>9 Q. A young man. Do you know anything</p> <p>10 about Mr. Brooks' preJune '98 activity level and</p> <p>11 abilities in terms of his functioning?</p> <p>12 A. I do not.</p> <p>13 Q. I am doing the best I can, doctor. I</p> <p>14 know you are pressed for time.</p> <p>15 (Discussion off the record.)</p> <p>16 Q. Going through your report, at page</p> <p>17 two, where it says it is possible that Mr. Brooks</p> <p>18 may have had pulmonary involvement from</p> <p>19 polymyositis, we have talked about that. You</p> <p>20 can't state to a probability that he had such</p> <p>21 pulmonary involvement; true?</p> <p>22 A. I cannot state that.</p> <p>23 Q. As far as his cardiac condition, can</p> <p>24 we agree that the cardiac condition that was</p> <p>25 described both at autopsy and in the records,</p>	<p style="text-align: right;">72</p> <p>1 not have ventricular hypertrophy or cardiomegaly.</p> <p>2 Q. Can you state to what extent from a</p> <p>3 quantification standpoint?</p> <p>4 A. I cannot.</p> <p>5 Q. Fair enough. Mr. Brooks did not have</p> <p>6 the presence of Jo-1 or SRP antibodies, did he?</p> <p>7 A. Not that I saw in the record.</p> <p>8 Q. And certainly Jo-1 and SRP antibodies</p> <p>9 are also poor prognostic features; correct?</p> <p>10 A. Yes, they are thought to be, yes.</p> <p>11 Q. Just for my edification, Jo-1 antibody</p> <p>12 is what?</p> <p>13 A. Jo-1, I believe, is, it's an anti-tRNA</p> <p>14 synthetases. I think it's Histadyl tRNA</p> <p>15 synthetases, but I am not sure which one. There</p> <p>16 are several. Jo-1 is a major one and there are</p> <p>17 other ones.</p> <p>18 Q. In your report, you state that</p> <p>19 Mr. Brooks would have had an extremely low</p> <p>20 probability of functional recovery to his</p> <p>21 premorbid status and considerably diminished</p> <p>22 survival compared with that expected in a</p> <p>23 65-year-old man with his premorbid health</p> <p>24 status.</p> <p>25 Without repeating everything that you</p>

<p style="text-align: right;">73</p> <p>1 have already told me, can you elaborate on that 2 beyond what you have already said or do you feel 3 that you have explained the basis or bases for 4 that statement adequately? 5 A. Most individuals with this disease -- 6 and I would say more than 80 percent -- do not 7 recover premorbid functional muscle strength. 8 Premorbid muscle strength; that is the muscle 9 strength they had prior to acquiring the 10 disease. More than 80 percent do not recover 11 full muscle strength. 12 Q. So that would be the muscle strength 13 that he would have had before May of 1998? 14 A. Exactly. So it's a very low 15 likelihood of full recovery, in anybody, in 16 everybody, in my patients. In the patients I am 17 treating now, most of them are on continuing 18 treatment for that reason. They still have 19 weakness. 20 Q. Okay. 21 A. I don't know if you want me to expound 22 on that further? 23 Q. I guess I want to understand beyond 24 what you have already shared with me as we have 25 talked about.</p>	<p style="text-align: right;">75</p> <p>1 facility; true? 2 A. Depending on the home situation. 3 Q. If he has a caring wife? 4 A. If the family was very supportive, he 5 could be managed at home. That would be optimal. 6 Q. Do you have any evidence from what you 7 have reviewed that he didn't have that kind of 8 family support that he would be able to be cared 9 for at home? 10 A. I didn't review those issues. 11 MR. MISHKIND: Give me a minute or two 12 to review my notes. 13 (Recess had.) 14 Q. You have referenced a number of 15 articles or authors, as well as you talked about 16 some studies. Are you aware of any studies that 17 have been generated from Case Western Reserve 18 University that specifically deal with the issue 19 of morbidity and mortality associated with 20 polymyositis? 21 A. Yes. There was a rheumatologist who 22 is now retired, whose name -- oh, Paul Vignos 23 V-I-G-N-O-S. He was a rheumatologist at 24 University Hospital for many years. He has been 25 retired, oh, probably for five or ten years now.</p>
<p style="text-align: right;">74</p> <p>1 A. There are certainly grades of 2 improvement. While I do not believe that, I 3 think very few people recover full functional 4 status, a substantial number can recover 5 acceptable or functional muscle status, so they 6 can carry out activities, they can be ambulatory 7 and do their hair, do their housework, et 8 cetera. 9 But then there are, of course, the 10 minority who do not recover even that kind of 11 functional recovery, and unfortunately, based on 12 Mr. Brooks' presentation, I believe he is likely 13 to be among the minority who does not have that 14 degree of functional recovery. 15 Q. And again, you have stated that at 16 best, he would have had a 50-50 likelihood of 17 being ambulatory? 18 A. Yes. 19 Q. And if he didn't respond to the 20 immunosuppressant therapy and fell below that 21 50-50, he would be probably needing a wheelchair 22 to get around? 23 A. That's correct. 24 Q. But would have been able to live 25 independent at home as opposed to in a long-term</p>	<p style="text-align: right;">76</p> <p>1 Certainly five years. 2 He did a lot of work in polymyositis. 3 This would have been back in the '70s and '80s. 4 And he was, I think, a highly regarded 5 investigator in this area. I don't recall any of 6 his papers specifically. They are from the '70s 7 and '80s and I don't use that literature that old 8 anymore, but he was a well regarded investigator. 9 Q. Well, there has been some suggestion 10 that there is some current literature that's 11 emanating or been published from Case Western 12 Reserve University dealing with the issue of 13 polymyositis, morbidity and mortality issues. 14 Are you aware of any such literature? 15 A. No, I'm not. Not recently. 16 Q. What you are familiar with goes back 17 to the '70s and '80s, and we talked about the 18 advances that have taken place both with regard 19 to treatment and with regard to the issue of 20 morbidity and mortality; true? 21 A. Yes. 22 Q. Do you have any type of a working 23 relationship with The Cleveland Clinic? 24 A. Personally, me? 25 Q. Yes.</p>

<p style="text-align: right;">77</p> <p>1 A. I know the rheumatologist there. I 2 don't interact with him in terms of patient care 3 or research. 4 Q. You don't see patients from The 5 Cleveland Clinic? 6 A. Only if there is an insurance change 7 and they no longer can be seen there and they see 8 me. 9 Q. Do you know any of the physicians that 10 are involved in this case? 11 A. No. Well, during the last part of his 12 hospitalization, he was seen by a rheumatologist, 13 whom I know. This was on the last few days of 14 his life. 15 Q. Who is that? 16 A. I believe Dr. Scheetz saw him on a 17 couple occasions. 18 Q. Other than Dr. Scheetz, do you know 19 any of the other caregivers in this case? 20 A. No. 21 Q. Do you know Dr. Preston? 22 A. No. 23 Q. He apparently has a specialty in 24 neuromuscular disorders. Did you gather that 25 from his deposition testimony?</p>	<p style="text-align: right;">79</p> <p>1 polymyositis? 2 A. Six that I can recall. There may be 3 others that I see less frequently who are managed 4 by other physicians. 5 Q. Have you ever treated a patient 6 similar to Mr. Brooks? 7 A. Yes. 8 Q. How long ago or is that one of the 9 six? 10 A. No, this was the man some 10 or 15 11 years ago who died, and he had a feeding tube. 12 Q. Was this the 48-year-old man? 13 A. Yes. 14 Q. How long did he live from the time of 15 diagnosis until the time he died? 16 A. I don't recall exactly. I think it 17 was probably in the neighborhood of four years, 18 four or five years. 19 Q. I take it your license has never been 20 suspended or revoked? 21 A. That's correct. 22 Q. You have never had privileges denied 23 at any hospital, have you? 24 A. No. 25 Q. Beside this gentleman that died, have</p>
<p style="text-align: right;">78</p> <p>1 A. I didn't specifically notice that. I 2 saw that he was a neurologist. 3 Q. Would you agree that polymyositis is 4 treated both by rheumatologists as well as by 5 neurologists? 6 A. I am sure that it is. 7 Q. And certainly, neurologists that have 8 a special interest in neuromuscular disorders 9 would be more likely to see patients as a subset 10 of neurologists than a general neurologist; 11 correct? 12 MR. KILBANE: Objection. 13 A. I suppose that would be true. 14 Q. So that while you and Dr. Preston may 15 have a difference of opinion in terms of the 16 likelihood of Mr. Brooks' long-term survival and 17 morbidity, you don't have any reason to believe 18 that Dr. Preston is not qualified to provide 19 opinions as it relates to the issues of morbidity 20 and mortality, are you? 21 MR. KILBANE: Objection. 22 A. I don't have any reason to believe 23 that. 24 Q. You told me you have about six 25 patients that you treat now that have</p>	<p style="text-align: right;">80</p> <p>1 you ever had any other of your patients with 2 polymyositis that had PEG tubes? 3 A. I can't recall. 4 Q. Did this gentleman that had the PEG 5 tube develop any type of an intraabdominal 6 hemorrhage following the PEG tube placement? 7 A. No. 8 Q. Do you have an opinion in this case as 9 to the etiology of his polymyositis? 10 A. No. 11 Q. More often than not, it's idiopathic, 12 is it not? 13 A. Yes. 14 Q. There are certain circumstances where 15 you can trace a probable explanation or am I 16 inaccurate? 17 A. In those cases, it's not called 18 polymyositis. There are certain drugs that will 19 induce a myopathy which looks like polymyositis 20 and certain viruses can induce a myopathy that 21 looks like polymyositis. Those are called viral 22 induced or drug induced, but this is idiopathic, 23 meaning by definition, unknown cause. 24 Q. He had a diagnosis of rhabdomyolysis 25 when he was admitted to the hospital?</p>

<p style="text-align: right;">81</p> <p>1 A. That's correct.</p> <p>2 Q. Is that a component of polymyositis?</p> <p>3 A. It can be. In patients with severe</p> <p>4 muscle injury, the muscle can become necrotic and</p> <p>5 then you get rhabdomyolysis.</p> <p>6 Q. Is that most likely what had caused</p> <p>7 some of the liver enzyme changes?</p> <p>8 A. Actually, in this case, the liver</p> <p>9 enzyme changes were probably muscle enzyme</p> <p>10 changes.</p> <p>11 Q. Secondary to the --</p> <p>12 A. Muscle necrosis.</p> <p>13 Q. From the polymyositis?</p> <p>14 A. Yes.</p> <p>15 Q. Is there any association between</p> <p>16 alcoholism and polymyositis?</p> <p>17 A. Not that I'm aware of.</p> <p>18 Q. There has been some talk about</p> <p>19 Mr. Brooks having had a history years ago of</p> <p>20 drinking.</p> <p>21 Is that in any way a factor, as you</p> <p>22 see it, in terms of his onset of polymyositis or</p> <p>23 the likely course with regard to his</p> <p>24 polymyositis?</p> <p>25 A. No. that doesn't seem to be a factor.</p>	<p style="text-align: right;">83</p> <p>1 usually younger individuals. In fact, all the</p> <p>2 ones I have seen have been younger individuals.</p> <p>3 They usually have a very rapid response in terms</p> <p>4 of all kinds of features, their strength, their</p> <p>5 weakness, their muscle enzymes to steroids.</p> <p>6 They usually have not had dysphasia,</p> <p>7 have usually not had truncal weakness. He does</p> <p>8 not fit any of these characteristics of this</p> <p>9 small group who has a dramatic rapid</p> <p>10 improvement. I would say his likelihood of being</p> <p>11 in this category would be less than one percent,</p> <p>12 and maybe less than .5 percent.</p> <p>13 Q. Can you state to a probability what</p> <p>14 complications, if any, Mr. Brooks would have</p> <p>15 experienced, even with a favorable response to</p> <p>16 rehab, becoming ambulatory, by being maintained</p> <p>17 on the steroids?</p> <p>18 A. The major complications of steroids</p> <p>19 include infections, which are always a risk. And</p> <p>20 a number of other complications, avascular</p> <p>21 necrosis of bone, diabetes, cataracts,</p> <p>22 osteoporosis, hypertension, aggravation of</p> <p>23 atherosclerotic disease, those are some of the</p> <p>24 factors.</p> <p>25 Q. When would he have developed those</p>
<p style="text-align: right;">82</p> <p>1 Q. So it would be irrelevant; true?</p> <p>2 MR. KILBANE: Objection.</p> <p>3 A. Yes.</p> <p>4 Q. How long would Mr. Brooks likely have</p> <p>5 been on steroids?</p> <p>6 A. Years.</p> <p>7 Q. Tapered again?</p> <p>8 A. Tapered.</p> <p>9 Q. There are studies, are there not,</p> <p>10 doctor, that patients that have a severe onset</p> <p>11 with an early diagnosis are tapered off of</p> <p>12 steroids?</p> <p>13 A. There are some patients who seem to go</p> <p>14 into remission and can go off steroids, yes.</p> <p>15 Q. And again, because we did not have the</p> <p>16 benefit of time in terms of testing Mr. Brooks'</p> <p>17 response, are you able to rule out his ability to</p> <p>18 have come off of steroids as he went through his</p> <p>19 rehabilitation?</p> <p>20 A. His probability for doing so would be</p> <p>21 extremely small.</p> <p>22 Q. Why?</p> <p>23 A. I have seen a few such individuals</p> <p>24 with an abrupt presentation who have gone into</p> <p>25 remission and gone off steroids. They are</p>	<p style="text-align: right;">84</p> <p>1 complications?</p> <p>2 A. Infections are a risk at any time.</p> <p>3 Q. But can you tell me, number one, that</p> <p>4 he would have developed an infection?</p> <p>5 A. I cannot say that for certain. I</p> <p>6 would say that the likelihood is considerable.</p> <p>7 Q. At what stage?</p> <p>8 A. At some point. One can't define when</p> <p>9 that would be.</p> <p>10 Q. Okay.</p> <p>11 A. Most individuals on long-term steroids</p> <p>12 do eventually get infections of some type,</p> <p>13 urinary tract infection, respiratory infections,</p> <p>14 in which steroids are thought to be a</p> <p>15 contributing factor.</p> <p>16 Q. And that would need to be treated</p> <p>17 accordingly?</p> <p>18 A. It would need to be treated.</p> <p>19 Q. You can't tell me when he would</p> <p>20 experience such an infection, if at all?</p> <p>21 A. That's true.</p> <p>22 Q. Or what would be the nature of the</p> <p>23 infection?</p> <p>24 A. That's correct, as well.</p> <p>25 Q. A vascular necrosis, can you tell me</p>

<p style="text-align: right;">85</p> <p>1 when he would've developed a vascular necrosis? 2 A. No. 3 Q. Or whether he would have developed it 4 at all? 5 A. No, I can't say that. 6 Q. And the impact on his underlying 7 coronary artery disease, can you tell me what 8 impact, if at all, that would have had on his 9 underlying coronary artery disease? 10 A. It would have aggravated it. 11 Q. Can you tell me how it would have 12 manifested itself? 13 A. It might have manifested itself in 14 terms of angina, myocardial infarction, 15 congestive heart failure. 16 Q. When would those things have likely 17 occurred? 18 A. Usually those occur after several 19 years of therapy. 20 Q. Are you saying that Mr. Brooks would 21 have after several years of therapy experienced 22 these problems or is it impossible for you to say 23 that he would have experienced those problems? 24 A. He could have. 25 Q. That's the best that you can do?</p>	<p style="text-align: right;">87</p> <p>1 in terms of the use of the word well. Most 2 patients do have a response. It's almost always 3 a partial response. It's almost never a complete 4 response. But it can be anywhere from a good 5 response to a poor response, anywhere within that 6 range. 7 Q. Are you intending to testify that 8 Mr. Brooks would have had a poor response to the 9 immunosuppressant therapy? 10 A. No. 11 Q. If a patient is treated successfully, 12 recognizing, again, that it's a disease that can 13 be treated but can't be cured, is the greatest 14 morbidity the side effects or the potential side 15 effects of the steroids? 16 A. I think that's probably the case, the 17 side effects of the steroids, the side effects of 18 immunosuppressants, as well, but both of those in 19 combination provide, contribute substantially to 20 the morbidity. 21 Q. You watched the labs on patients that 22 are on immunosuppressant therapies; true? 23 A. Right. 24 Q. You look for anemias? 25 A. Right.</p>
<p style="text-align: right;">86</p> <p>1 A. Right. 2 Q. Fair enough. 3 Are there any articles that have been 4 published from Metro or from UH that are of 5 recent vintage besides the one we talked about 6 with Dr. Vignos that deal with pharyngeal 7 dysfunction and prognostic factors? 8 A. Not that I'm aware of. 9 Q. Will you be able to provide me in the 10 literature or perhaps give me a name of an author 11 that you believe has provided this opinion that 12 correlates severe weakness at the onset of 13 polymyositis with a poor prognosis? 14 A. I'm sure I can find such references in 15 the literature. 16 Q. As you sit here now, do you know of 17 any studies that specifically correlate severity 18 in weakness at onset with a poor prognosis? 19 A. I can't think of one right off the 20 bat, no. 21 Q. Most patients that are on 22 immunosuppressant therapy and steroids respond 23 well to the therapy; true? 24 MR. KILBANE: Objection. Go ahead. 25 A. The question is -- I have a question</p>	<p style="text-align: right;">88</p> <p>1 Q. You look for any evidence of leukemia? 2 A. Right. 3 Q. Not all patients on immunosuppressants 4 develop the malignancies; true? 5 A. That's correct. 6 Q. In fact, a very small percentage do? 7 A. That's correct. 8 Q. No reason to believe that he would 9 have developed any type of malignancy associated 10 with the immunosuppressant therapy; true? 11 A. Not associated with the 12 immunosuppressant therapy. It's still 13 approximately a ten percent chance that he could 14 have developed a malignancy related to having the 15 polymyositis over the next two years. 16 Q. Ninety percent likelihood that he 17 wouldn't? 18 A. Approximately, yes. 19 Q. We have talked about your report. I 20 believe we have gone through it in terms of the 21 factors which you have relied upon in terms of 22 indicating the long-term disability and the 23 impact on his life expectancy. 24 As you look at your report and as you 25 think about what we have talked about, do you</p>

<p style="text-align: right;">89</p> <p>1 believe that there are any other opinions that 2 you hold in this case that we have not talked 3 about, doctor? I want to give you, in fairness, 4 an opportunity to express those before we 5 conclude. 6 MR. KILBANE: Objection. 7 A. I think that my report pretty well 8 sums up exactly the way I think, the way I feel 9 about this case in terms of his prognosis. 10 Q. And have we pretty much exhausted the 11 specifics of your report as we have been chatting 12 here for the last couple hours? 13 MR. KILBANE: Objection. 14 A. Well, as far as I'm aware at the 15 moment, yes. 16 Q. Have you been asked to look at any 17 additional information or do any additional 18 research between now and trial in two and a half 19 or three weeks? 20 A. No. 21 MR. MISHKIND: Thank you for your 22 time. 23 (Deposition concluded at 10:45 a.m.) 24 25 CERTIFICATE State of Ohio,</p>	<p style="text-align: right;">91</p> <p>1 INDEX 2 EXAMINATION OF STANLEY P. BALLOU, M.D. 3 BY MR. MISHKIND: 3 12 4 Exhibits 1 thru 4 were marked.....3 3 5 Exhibit 2-A was marked..... 8 3 6 Exhibit 5 was marked..... 14 3 7 Exhibit 6 was marked..... 17 18 8 Exhibit 7 was marked..... 22 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>
<p style="text-align: right;">90</p> <p>1 SS: 2 County of Cuyahoga. 3 I, Vivian L. Gordon, a Notary Public within 4 and for the State of Ohio, duly commjsioned and 5 qualified, do hereby certify that the within 6 named STANLEY P. BALLOU, M.D. Was by me first 7 duly sworn to testify to the truth, the whole 8 truth and nothing but the truth in the cause 9 aforesaid; that the testimony as above set forth 10 was by me reduced to stenotypy, afterwards 11 transcribed, and that the foregoing is a true and 12 correct transcription of the testimony. 13 14 I do further certify that this deposition 15 was taken at the time and place specified and was 16 completed without adjournment; that I am not a 17 relative or attorney for either party or 18 otherwise interested in the event of this action. 19 20 IN WITNESS WHEREOF, I have hereunto set my 21 hand and affixed my seal of office at Cleveland, 22 Ohio, on this 27th day of November, 2000. 23 24  25 Vivian L. Gordon, Notary Public Within and for the State of Ohio My commission expires June 8, 2004. 17 18 19 20 21 22 23 24 25</p>	

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