

1 determine what the normal time is. No?

2 MS. STEINBERG: We don't know, your Honor.

3 JUDGE DAVIDSON: How about a date for briefs?

4 First of all, don't make it too long, because I'm going
5 to limit them, and the first limitation I'm putting in
6 is -- as I said, I can't tell you how to organize it
7 but I would appreciate it if you would organize your
8 briefs in such a manner as to A, follow along with the
9 issues in this proceeding. That is, you start with
10 whether or not the Agency has met its threshold
11 obligation of requiring the burden going forward to
12 shift to the manufacturer to prove safety and efficacy.

13 And that, I think, is well-documented in our
14 previous motions and discussions and things, the fact
15 that there is a threshold burden on the Agency doesn't
16 necessarily constitute, quote, unquote, new evidence,
17 but it does include a look at the evidence, a new look
18 at the evidence which justifies a finding that the
19 prior finding is no longer valid and therefore the
20 burden of going forward would shift to the
21 manufacturer.

22 So that's the first issue I'd like you to

1 discuss.

2 After that, I'd like you to organize your
3 briefs in such a way as to deal specifically, if we get
4 to that, and in Bayer's point I guess that would be in
5 the alternative, dealing with the rest of the evidence
6 and the proceedings in line with the issues as
7 presented in the NOH.

8 Now, I want you to do all that in 10 pages. I
9 would like you to do it in as few pages as possible,
10 but I will admit for the record that I don't claim to
11 be a statistician, I don't claim to be a scientist, so
12 I'm going to need you to refer to the evidence, not
13 your own ideas of what this is, but what the evidence
14 shows, in a way that witnesses have supposedly
15 explained all this and in simplified terms to me.

16 It's not you explaining it to me; it's the
17 witnesses having explained it to me in their testimony
18 or in the transcript. And back to the old simplify,
19 simplify. That's what I need. If you want me to read
20 your conclusion in a reasonable amount of time, I've
21 got to understand what I'm doing.

22 So far I think I'm sticking with it pretty

1 good, but a lot of the technical stuff I want you to
2 point to where the witnesses have made it clear,
3 because that's why they're witnesses, in order to
4 explain to the so-called novice what they're talking
5 about.

6 Along those lines, I do not expect you to
7 reproduce testimony in your brief. I do not expect you
8 to reproduce things that are already in the record;
9 references would be sufficient. But I caution you that
10 they have to be accurate and the citations have to
11 reflect what they're cited for, otherwise I'm going to
12 just throw them out.

13 Okay. I've wrestled with the idea -- I
14 usually have concurrent briefs, but because of my
15 admission, my own lack of statistical expertise and
16 scientific expertise, I'm thinking that I might allow
17 reply briefs.

18 They'd still be concurrent, but an opportunity
19 to reply, which even means that maybe it will be five
20 pages initially instead of ten.

21 Anybody have any thoughts on that pro, con, or
22 otherwise with respect to the concurrent reply briefs?

1 MS. STEINBERG: CVM is in favor of that.

2 MR. NICHOLAS: Bayer is in favor of that, your
3 Honor.

4 JUDGE DAVIDSON: All right. How about 100
5 pages initially, 50 pages in reply? And I've got to be
6 able to read it, so don't give me this tiny little
7 print just so you can get it into a hundred pages.

8 Okay. Due date. I'll take your suggestions
9 and then I'll rule. And we'll allow two weeks for the
10 transcript to be completed. You can go from there.
11 Anybody care to venture a stab?

12 MR. NICHOLAS: I was going to suggest, your
13 Honor, that we confer with CVM and then get back to you
14 tomorrow morning on that, if that's acceptable?

15 MS. STEINBERG: Your Honor --

16 JUDGE DAVIDSON: Yeah.

17 MS. STEINBERG: Instead of waiting until
18 tomorrow, would it make sense for us to confer in the
19 next few minutes?

20 JUDGE DAVIDSON: If you think you can. I want
21 to tell you, you know, I don't give -- I'm not talking
22 two, three months here.

1 If you can come up with something reasonable
2 within that time frame, including the replies, maybe it
3 will be all right.

4 I'll go off the record and you sit down and
5 talk and come back with your proposal for briefs and
6 reply briefs. I have a calendar here so I should be
7 able to make sure that you're not required to file
8 anything on a Saturday or Sunday. I won't guarantee
9 the holidays.

10 Off the record.

11 (A discussion was held off the record.)

12 MS. STEINBERG: Your Honor, during the recess,
13 counsel for Bayer and counsel for CVM conferred and we
14 have a joint proposal for due dates. We propose that
15 the initial brief be due July 18 and that the reply
16 briefs be due August 15.

17 JUDGE DAVIDSON: July 18 is my anniversary.
18 I'll be married 45 years on July 18.

19 MR. NICHOLAS: The 19th?

20 JUDGE DAVIDSON: That will be the Saturday.

21 MR. NICHOLAS: A present on the 18th.

22 JUDGE DAVIDSON: Oh, God, no.

1 MR. NICHOLAS: Your wife would kill us.

2 JUDGE DAVIDSON: All right. July 18. I knew
3 there was something familiar about that. Two months.
4 You better do a decent job, I'm giving you so much
5 time.

6 MR. NICHOLAS: You've given us such a
7 challenge, your Honor, we need it.

8 JUDGE DAVIDSON: And the response you said was
9 August?

10 MS. STEINBERG: August 15.

11 JUDGE DAVIDSON: Done.

12 MR. NICHOLAS: Thank you, your Honor.

13 MS. STEINBERG: Thank you, your Honor.

14 MR. SPILLER: Thank you, your Honor.

15 JUDGE DAVIDSON: Now remember what I said
16 about -- I'd just as soon not have any more evidence
17 come in unless it really qualifies as, quote, new
18 evidence, because administrative proceedings, that's
19 always acceptable if something new really comes in that
20 is of that kind of merit that requires, in effect,
21 reopening the proceeding.

22 Otherwise, we are adjourned.

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MR. SPILLER: Thank you, your Honor.

MR. NICHOLAS: Thank you, your Honor.

MS. STEINBERG: Thank you, your Honor.

(Whereupon, at 3:10 p.m., the hearing was
concluded.)

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