

1 presented. We can say that doses are recommended up
2 to 5 mg and present the data. And here is the
3 toxicity -- here's the toxicity on this, here's the
4 toxicity on that, and here's the response on the 2 as
5 well as on the 5.

6 But they presented data that showed that
7 this was safe and efficacious at 5 mg. You have to
8 note that there is more toxicity when you go up to 6
9 milligrams. You have multiple comparisons in the
10 group that had 5. But that was presented. It had
11 hundreds of patients exposed to that. What's wrong
12 with that?

13 DR. GOLDBERGER: There's a couple of
14 things. First of all, you know, there's been a
15 suggestion about putting the clinical trial results in
16 the label without making -- you know, which would
17 include the 5 mg dose without making a recommendation
18 for the 5 mg dose.

19 There is a concern in the FDA that
20 essentially putting it in the label, for instance in
21 the clinical trial section, is in many respects,
22 including from a promotional perspective,

1 indistinguishable than from granting the indication
2 for 5 mg.

3 So we do have some concerns if on one hand
4 you feel the data should be there yet on the other
5 hand people don't feel there's enough evidence to
6 warrant using the 5 mg. So that's a schism that if it
7 could get closed a little I think would be very
8 helpful.

9 The other comment I would make, as I see
10 Dr. Hunsicker perhaps is getting more interested in
11 getting the package insert -- the other comment I
12 would make is, going back to my original comments
13 before we started the questions is, the package insert
14 needs to be clear on what people ought to do.

15 It should not be written for those people
16 who have enormous expertise in the area, who probably
17 won't in fact, sometimes read it anyway. It should be
18 written for the broad range of practitioners who might
19 be likely to use the drug.

20 So if there are circumstances where you
21 feel that the information is sufficient for the 5 mg,
22 that's fine. But it ought to be clearly spelled out

1 in the labeling.

2 CHAIRMAN MASUR: Why don't we go back to
3 Larry and then we can simply open it so people can
4 suggest how it could be worded. Not working with the
5 wording but with the direction of it. Larry.

6 DR. HUNSICKER: Responding to your
7 comment, Mark, I would not be worried if people used
8 this at a 5 mg dose. I agree that the evidence for
9 excessive toxicity is not great and you can back off.
10 It's usually easier to manage toxicity than it is to
11 deal with. You don't know that you're under-
12 immunosuppressed.

13 So if you -- the reason I have problems
14 with 5 mg is simply I have no idea that 5 mg is right
15 in whom or what. All I know is that there was some
16 evidence some people seemed to do better with more.
17 But if you need a number, I would agree with Sue then;
18 five is what was done, put it in there. It's not
19 going to hurt anything. Just don't tell them it's
20 truth.

21 CHAIRMAN MASUR: Suthan, how would you
22 extract what's true about the dosage?

1 DR. SUTHANTHIRAN: I would say recommend
2 a dosage that's 2 to 5 mg, significant improvement in
3 cadaveric donor with 5 mg, however the toxicity is
4 significantly higher with 5 mg also.

5 CHAIRMAN MASUR: It sounds like a non-FDA
6 way of doing things, but go ahead. Jim.

7 DR. LIPSKY: In a different life I
8 practice general internal medicine and I'd let FDA
9 know there's no way I'm going to pick up this drug,
10 look at the package insert and start dosing a patient.
11 This is going to be a drug that is going to be, I
12 believe, used in the vast majority of people.

13 My colleagues around the table who have a
14 great deal of experience with transplantation, et
15 cetera, just like the people with the black boxes
16 with the aphalagic agents. Now, maybe from data, if
17 you get a psoriasis indication or something like that,
18 I presume that the box would give some very discrete
19 dosage information that would tell me as a general
20 Internist what to do.

21 But I would -- if I had a patient come to
22 me who had undergone renal transplant, it would go to

1 someone who was very expert in that field.

2 DR. GOLDBERGER: Well, I guess the sense
3 is that although there is not sufficient information
4 to clearly support the alternate dose in exactly
5 defined population, in some way at least some members
6 of the committee would like some comment suggesting
7 that an alternate dose ought to be considered in
8 certain circumstances. Is that a reasonable summary?

9 If that's a reasonable summary then it
10 will be our problem to try to work through that and
11 fit that within the appropriate regulatory
12 constraints, and we will work with the company on
13 that.

14 CHAIRMAN MASUR: Does anyone either want
15 to have the last word on this topic or bring up an
16 area at this point that we have not touched on yet?

17 If not, then we very much appreciate --
18 sorry.

19 DR. CHAVERS: I have an additional. I
20 think we need to begin to accumulate data on
21 cardiovascular risk factors, especially since the
22 cardiovascular deaths were the greatest cause of

1 deaths. And with patients experiencing hyperlipidemia
2 I'd like a little bit more information about other
3 risk factors.

4 CHAIRMAN MASUR: Okay, we appreciate the
5 sponsor providing clear information. We appreciate the
6 FDA analysis and thanks you very much for staying
7 until the bitter end.

8 (Whereupon, the meeting was concluded at
9 3:08 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript in
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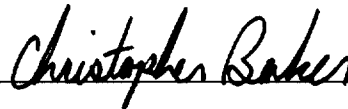
RAPAMUNE (SIROLIMUS), WYETH-AYERST
LABORATORIES

Before: ANTIVIRAL DRUGS ADVISORY MEETING
IMMUNOSUPPRESSIVE DRUGS SUBCOMMITTEE

Date: JULY 27, 1999

Place: GAITHERSBURG, MARYLAND

represents the full and complete proceedings of the
aforementioned matter, as reported and reduced to
typewriting.



Look-See Concordance Report

- 8 -

UNIQUE WORDS: 3,388
 TOTAL OCCURRENCES: 20,658
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 TOTAL WORDS IN FILE:
 51,369

SINGLE FILE CONCORDANCE

CASE SENSITIVE

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