

1 evaluated. Their linearity claims are unsubstantiated
2 because the imprecision is too high in the test group
3 to detect a non-linearity."

4 "They claimed their method agreed with the
5 CRMLN lab at Pacific Biometrics, but I evaluated the
6 predicted values they would obtain in the following
7 table."

8 I don't have a way to project the table.
9 But at 100 from Pacific Biometrics, the device reads
10 80. The bias is 20. Pacific Biometrics, 200, device
11 176. Bias 12. At 300, Pacific Biometrics, device
12 272. It sounds like he is plugging numbers into the
13 regression equation and looking at bias from the
14 device. Four hundred, 368, eight percent bias. Five
15 hundred, 464, seven percent bias.

16 "All these biases are well over the
17 allowable five percent. The package insert fails to
18 state the intended medical use of this device. It
19 understates the necessity for using a fasting sample.
20 Martin H. Kroll, M.D."

21 Okay. The hour is getting late, but we
22 still have time for some questions and answers and

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1 final recommendations. Are there any questions for
2 either the FDA or the sponsor from any of the panel?

3 Seeing none, does the sponsor have
4 anything that you would like to present at the end of
5 the panel now?

6 MR. CONNOLLY: Yes.

7 CHAIRPERSON NIPPER: We would appreciate
8 brevity. Thank you.

9 MR. CONNOLLY: I think I agree. I
10 definitely agree that the product should be near the
11 guidelines. I didn't realize how far away from the
12 guidelines it was. We have talked about this at lunch
13 at great length, or as much time as we had. I think
14 this product can and will meet or come very close to
15 those guidelines.

16 Whole blood is a tough issue. I think
17 calibrating against the CRMLN method, for some reason,
18 there is some bias here. I'm not sure what it is, as
19 to why we got it, but it's definitely there. We have
20 seen that. That needs to go away. If that bias goes
21 away, that takes away a good part of that failure to
22 meet that 15 percent number.

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1 The precision issue, I'm not too sure
2 about. I can't really address that right now. It
3 definitely needs more high end samples. I don't think
4 there were more than three or four in this area that
5 we are looking at, not necessarily as a cutoff, but
6 there just needs to be more data in that end.

7 So I think we can nearly meet them. The
8 guy that came up with 17.5, loved him. The guy with
9 the 20 percent, I thought I liked even better. But I
10 think we can get very close to those numbers, in that
11 the 400 milligram, I think it's probably incorrect to
12 say that that was close. There are not enough numbers
13 there to accurately justify that 15 percent or 14.9.
14 But I am sure the product can meet them.

15 It is embarrassing to stand up here and
16 say you can meet them, and then obviously you didn't,
17 but that's why I get those big dollars.

18 The labeling issues were extensive and
19 that's something that needs a lot of work, but that's
20 something that is fixable, I think, in most of those
21 things. The drug interferences are easy enough to
22 test. This is no more than a day or two's work to

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1 find out what drugs someone has in mind, get a list
2 together, or go back through some other 510Ks for
3 triglycerides used in other parts of the market, see
4 what drugs they did, and just do the same thing,
5 assuming the question would apply to them.

6 The precision data, it is impossible to do
7 this day-to-day. So I would recommend a better way of
8 doing this. That is to not only take more patients,
9 definitely more patients, but you just can't get
10 somebody to cough up a 200 milligram triglyceride
11 daily. So I think one patient running -- and it's
12 tough on your fingers, because we do this for
13 calibration. One patient running maybe 10, maybe 15
14 tests in a 15-minute time period, and let that patient
15 do that a number of days in a row, maybe 10 days in a
16 row, then you get some idea of what the precision is
17 on a particular patient. There is just no other way
18 to do that for any test. They are just not static.

19 So I suggest we replace that precision
20 data with whatever the number is, 10 patients, 20
21 patients, and let them do as many finger pricks as
22 their sore little fingers tolerate.

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1 The minimum sample size, we couldn't
2 address that because we don't have the right person
3 here to address that. Then I realized the minimum
4 sample size you were talking about were statistical
5 issues instead of sample volume. So disregard that.

6 Again, the frequency of testing and where
7 some of these numbers come from, I think we're in
8 uncharted waters where over-the-counter consumer tests
9 are. You take things from other package inserts and
10 use them. Some of them are not applicable. That is
11 what we did. Cut and paste is neat. It still needs
12 a lot of work, but I think it was -- we didn't know
13 what to put there, so we used something from something
14 else. Now we know how you feel about it.

15 I understand the issues with the two
16 inserts. I am not sure that I understand how to
17 resolve this. I definitely think they should be
18 better, as you pointed out in several areas. But as
19 to having one for everybody, I think is kind of -- I
20 don't think that is going to work either. Some of the
21 professionals are going to be --

22 CHAIRPERSON NIPPER: Let me interrupt. I

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1 think I can give you the sense of the panel, that two
2 may be okay, but one shouldn't refer to the other. In
3 other words, they should be stand-alone, and the over-
4 the-counter insert should be the same, should be
5 stand-alone, and not refer over to the professional.
6 That is what I heard anyway.

7 DR. REJ: I think there's a model in over-
8 the-counter pregnancy testing, where the technology
9 and the tests are very similar for professional use,
10 but there is no reference to the professional use
11 product in the over-the-counter.

12 MR. CONNOLLY: I'm not sure what happened,
13 but that's easy enough curable. We can fix that part
14 of it.

15 I had to listen to someone say I learned
16 a lot not too long ago. I guess I learned a lot
17 today. We are looking forward to bringing this back
18 here with the -- I don't like saying things that
19 aren't correct, especially when I know they can be
20 true. This doesn't reflect any of our other products,
21 as the reviewers know. They have not seen this kind
22 of data on our other products. So this one will have

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1 some more work done on it, and it will be back. Thank
2 you.

3 CHAIRPERSON NIPPER: We appreciate your
4 constructive response.

5 Is there other committee discussion?

6 Final recommendations? By going through
7 the questions, I believe we have made lots of
8 recommendations. We have heard the sponsor has
9 listened to those. Are there other recommendations
10 that those members of the panel who are still here
11 have to make to the sponsor or to the FDA?

12 Dr. Gutman, do you have any remarks?

13 MR. GUTMAN: No. We are just grateful for
14 all of your input. We'll look forward to working with
15 the sponsor to try and see if we can come up with a
16 better product.

17 CHAIRPERSON NIPPER: Do you have any
18 remarks, Ms. Calvin?

19 MS. CALVIN: No. I just wanted to thank
20 the sponsor, all of the FDA staff, and the panel of
21 course, and any public attendants that are here.

22 Also, I just wanted to make a note that

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1 the next Clinical Chemistry and Clinical Toxicology
2 Devices Panel meeting will be held on December 6 and
3 7 of this year.

4 CHAIRPERSON NIPPER: I would like to
5 reiterate Ms. Calvin's thanks to all the panel
6 members, the FDA staff, the sponsors for their hard
7 work. These days are expensive to do, both for the
8 Government as well as to the sponsor. I think I can
9 speak for all the members of the panel when we say
10 that we hope that there has been benefit and payback
11 for the work required to get this meeting together.

12 I would like to thank you for your hard
13 work and your attention. I am glad we're as close to
14 the time as we are. The Chair will entertain a motion
15 to adjourn if there is no further business.

16 DR. REJ: So moved.

17 CHAIRPERSON NIPPER: Second?

18 DR. EVERETT: Second.

19 CHAIRPERSON NIPPER: All in favor? We are
20 adjourned. Thank you.

21 (Whereupon, at 4:35 p.m., the proceedings
22 were adjourned.)

CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: OPEN SESSION MEETING

Before: CLINICAL CHEMISTRY AND CLINICAL
 TOXICOLOGY DEVICES PANEL

Date: OCTOBER 28, 1999

Place: ROCKVILLE, MARYLAND

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