

1 industry.

2 DR. SCOLNICK: I would not say that  
3 certainly about many of us sitting around the  
4 table. It may not be in other industries, but  
5 I think it is to us. Because when we evaluate  
6 our drugs, and there are three or four of us  
7 here, we collect safety data as well as  
8 efficacy data, and have to weigh that benefit-  
9 risk, and should be responsible, just as you  
10 are.

11 DR. LANGER: Bob, you wanted to make a  
12 comment?

13 DR. NEREM: It's sort of a follow on.  
14 He really triggered me to ask for the  
15 following, either in the way of written  
16 information or probably preferably a  
17 presentation.

18 I think I have some understanding,  
19 from a qualitative point of view about the  
20 research effort at FDA. I really don't have  
21 any hard data, and I'd like to know, because I

1 have a feeling there's a lot of differences  
2 between different centers as to how much money  
3 goes into research, how many people are  
4 involved in research. I'd like to understand  
5 what drives the research agenda of the  
6 different centers, because it may be driven by  
7 a totally different set of issues, and that's  
8 fine.

9 How do the different centers, because  
10 that's really where the research resides, how  
11 do they set an agenda and drive their research  
12 program?

13 DR. LANGER: We'll see what we can do  
14 on that.

15 Let me wrap up and just cover what I  
16 consider the action items, and follow-up, and  
17 people add or subtract to what I say.

18 On Doris Hare public comments, the  
19 Board will let the agency know what we  
20 recommend, and I have an e-mail in to everyone  
21 and a number of responses already.

1           Secondly, on the CDRH external review,  
2 CDRH is going to present an external review  
3 with Bob Nerem at the fall meeting. CDRH will  
4 consider the top ten things that Ed suggested,  
5 or David Letterman I think is how we look at it  
6 -- as part of the review. I think everybody,  
7 Bob Nerem were talking about how we were going  
8 to introduce this at promotion schedules at  
9 universities, so you've made a big impact.

10           DR. SCOLNICK: I won't be tarred and  
11 feathered for that one.

12           DR. NEREM: My idea, Ed, is that when  
13 you ask a faculty member to chose their best  
14 five papers, you should also ask them to give  
15 you their worst five papers.

16           DR. LANGER: That's right. We'll also  
17 consider looking at gender differences.

18           Third on the ORA external review,  
19 again consider the top ten. I'll look at both  
20 positive and negative. I thought that was very  
21 important what was said there. Second, look at

1     how data gaps in science are handled as part of  
2     the review; third, the scope may be too broad;  
3     consider continually reviewing components of  
4     ORA each year. Institutionalize the review.  
5     Fourth, review CFSAN's peer review to address  
6     comments about ORA.

7             And finally on the FDA University, I  
8     think this is clearly something we all want to  
9     continue and next time we should get an FDA on  
10    progress in this and continue this discussion.  
11    And maybe there should be some interchange in  
12    the meantime to get ready for that between some  
13    of the people here and members of the FDA.

14            Is there anything that I've forgotten,  
15    or anything should be modified?

16            [No response.]

17            Okay. Again, the comments I've heard  
18    from the FDA is that this is a terrific Board.  
19    I think everybody really appreciates the  
20    comments and suggestions; and I just want to  
21    thank everybody, on both sides, for I think a

1       terrific discussion today.

2                   Thanks very much.   And the next  
3 meeting is November 16.

4                   [Whereupon, at 2:53 p.m., the meeting  
5 concluded.]

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