

1 but this is an enormous vaccine program. It's one the  
2 public has learned to have confidence in and trust and  
3 I would like to know more about what's working and  
4 what's not working each year that we make these  
5 changes and put these vaccines out there.

6 And so I would like to see money, real  
7 money spent on monitoring the field performance of the  
8 vaccines each year. By tailoring some of this  
9 surveillance data that we collect so carefully and  
10 linking it up to the immunization status of the  
11 patients from whom the isolates came and trying to  
12 learn what's going on in terms of field performance  
13 from them.

14 So just a strong advocacy from my point of  
15 view and hopefully many others of the Committee as  
16 well.

17 DR. BAUM: With that, Bill, perhaps you  
18 can announce the results of the vote?

19 DR. FREAS: Okay, my unofficial tally is  
20 for the H1N1, 17 voted to keep it and there was one  
21 abstention. The industry rep favored the majority  
22 vote.

23 For the H3N2, there were 12 votes to keep  
24 the current strain. There were 5 to defer with one  
25 abstention and the industry went with the majority

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1 vote.

2 For the B, there were 16 votes to defer,  
3 1 vote to keep, industry went with the majority and  
4 there was one abstention.

5 DR. DAUM: You are quick.

6 DR. FREAS: I hope I'm right.

7 DR. MYERS: There was one vote for  
8 B/Victoria.

9 DR. FREAS: That is absolutely correct.  
10 There were 16 to defer, 1 to keep.

11 DR. GRIFFIN: It's was a change now.

12 DR. FREAS: Could somebody clarify that  
13 for me?

14 DR. GRIFFIN: It's a change of strain.  
15 It's a different strain than we're currently using.

16 DR. DAUM: Okay, Dr. Egan, let's call on  
17 you to keep things going.

18 DR. EGAN: Yes, I just wanted to make one  
19 quick comment about the B strains and the possibility  
20 of having two and the dose that might be used. I  
21 think our default position is that if there are going  
22 to be two B strains, then they're going to be at 15  
23 micrograms each unless there is data, compelling  
24 evidence that 7.5 will work, that is, that they are --  
25 that those two B antigens are cross protective. So I

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1 just wanted to raise -- to put forth this point to  
2 help prime some of the discussions that will be coming  
3 up next month or in March.

4 DR. DAUM: Thank you very much, Bill. My  
5 guess is that there wouldn't be anybody that wanted to  
6 change their deferral decision now based on that, but  
7 I think that it will influence how we think about what  
8 goes on next time. If I'm incorrect, and someone  
9 wants to reconsider based on that, please speak now.

10 Okay, with that having been done we'll  
11 move on to the open public hearing. This is an  
12 opportunity for anyone in the audience who wishes to  
13 to address the Committee. I don't think there's  
14 anyone scheduled.

15 In want of such a Committee addressing  
16 folks, we're adjourned. Thank you very much.

17 (Whereupon, at 3:29 p.m., the meeting was  
18 concluded.)

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22  
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24  
25

CERTIFICATE

This is to certify that the foregoing transcript in the  
matter of:                    Vaccines and Related Biological Products  
  Advisory Committee

Before:                        DHHS/FDA/PHS/CBER

Date                            January 30, 2002

Place:                         Bethesda, MD

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



A handwritten signature in black ink, appearing to be "K. M. Kelly", is written over a horizontal line.