

1 for anti-infectives, and there's always a statement  
2 about -- the general statement is disease due to  
3 susceptible organisms.

4 DR. CHESNEY: Just checking.

5 (Laughter.)

6 CHAIRMAN RELLER: And also the sponsor  
7 addressed that issue quite specifically about, you  
8 know, what is done subsequently, that susceptibility  
9 testing, if available, by reliable methods or when  
10 available, would be considered.

11 Dr. O'Fallon.

12 DR. O'FALLON: Well, I think that the  
13 safety is good. There's good data for that. Efficacy  
14 is, of course, much more problematic, but assuming  
15 that everybody is comfortable with using primates and  
16 comfortable with the idea that this one organism  
17 causes different kinds of problems and if it's good  
18 for one, it'll probably be effective for another;  
19 under those assumptions, yes.

20 CHAIRMAN RELLER: Dr. Soper.

21 DR. SOPER: Yes.

22 DR. CHRISTIE-SAMUELS: I'd say yes for

1 safety, with the reservation that in children we have  
2 information just for 104 over 60 days, and if we are  
3 going to be giving this drug to probably large  
4 populations, we should probably get more information  
5 maybe at that time.

6           Regarding efficacy, I'd say yes for  
7 adults, but I'm not so sure about children because I'm  
8 not sure that we heard anything about -- I don't know  
9 about the disease itself, pathology or anything was  
10 described in children. So I have a little reservation  
11 there as well.

12           But it's yes for that.

13           CHAIRMAN RELLER: Thank you.

14           Dr. Rodvold.

15           DR. RODVOLD: Yes for both.

16           CHAIRMAN RELLER: Yes.

17           And Dr. -- yes, Dr. Wittner.

18           DR. WITTNER: In view of the context of  
19 what this meeting is about and the seriousness and the  
20 reason for this meeting, I think the question is  
21 clearly yes. I would vote yes.

22           CHAIRMAN RELLER: And Drs. Chikami and

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1 Murphy, I think clearly from the sense of the  
2 committee that there is clear recognition of the  
3 special circumstances that you articulated, the  
4 sponsor articulated and it has come out under the  
5 discussion, that the unanimous yes is clearly linked  
6 with the specific purpose denoted and in the context  
7 that all the discussions took place.

8 Now, there has also been discussion and  
9 the data available presented on best estimate of  
10 duration of prophylactic therapy for inhalational  
11 anthrax in the event of an exposure, and also the  
12 recognition that the consensus recommendations  
13 currently are for 60 days.

14 So Question 2 is: is 60 days an  
15 appropriate duration of ciprofloxacin administration  
16 for post exposure prophylaxis of inhalational anthrax?

17 Dr. Wittner?

18 DR. WITTNER: Yes.

19 CHAIRMAN RELLER: I think so, yes.

20 Dr. Rodvold?

21 DR. RODVOLD: Yes, I believe so.

22 DR. CHRISTIE-SAMUELS: Yes, based on the

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1 information available.

2 DR. SOPER: Yes.

3 DR. O'FALLON: Yes.

4 DR. CHESNEY: Yes.

5 DR. ARCHER: Yes.

6 CHAIRMAN RELLER: Dr. Chikami, the advice  
7 of the Advisory Committee is that the FDA consider the  
8 request of sponsor for this supplemental indication  
9 for use of ciprofloxacin for prophylaxis for  
10 inhalational anthrax, post exposure prophylaxis.

11 What comments do you have and what else do  
12 you want us to do this afternoon?

13 DR. CHIKAMI: I think, first of all, I'd  
14 like to thank, first of all, our guests who sat on the  
15 panel and especially the guest who provided the talks  
16 in the early morning session because I think they went  
17 a long way in allowing us to, as you say, paint the  
18 appropriate context for the discussion of this very  
19 unusual and very difficult situation in regard to the  
20 available information and the sort of regulatory  
21 decisions that we need to face as we consider this  
22 application.

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1                   And I certainly appreciate the questions  
2                   and the discussion of the committee. I think I'd also  
3                   like to commend the review time also because this was  
4                   quite an unusual situation. They were faced with not  
5                   the usual application, and it had to be creative in  
6                   not only their review of the information at hand, but  
7                   also in their ability to go to the literature  
8                   independently and develop a familiarity with the topic  
9                   area, and I think they did a really excellent job, and  
10                  in particular, Dr. Meyerhoff whose presentation really  
11                  sort of summed up our overall perspective on the body  
12                  of information that needed to be assembled and  
13                  constructed in the decision making process.

14                 DR. MURPHY: Since you all have been so  
15                 efficient, I don't want to prolong people being able  
16                 to leave, but I did want to tell the committee that we  
17                 do appreciate their thoughtfulness and their  
18                 questions.

19                 We realize that there are many other  
20                 interesting aspects that one could address and talk  
21                 about. We just really were interested in wanting your  
22                 opinion about the ability to take this evidence and

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1 use it to label this product for the situation that  
2 you've heard about today.

3 And it is a unique situation, and we will  
4 take into consideration your comments about how your  
5 yes was provided in our deliberations about the  
6 labeling.

7 So I did want to again thank you, and of  
8 course, as I said in the beginning, for the time and  
9 the expertise that many others have provided at  
10 today's meeting.

11 CHAIRMAN RELER: Before closing, I'd like  
12 to thank the sponsor, Bayer, for their clear and  
13 complete presentation, Dr. Meyerhoff, who has worked  
14 so hard on this, and our guests for educating us  
15 further, specially Drs. Friedlander and Walker, and to  
16 my colleagues on the committee for their decisiveness  
17 in being able to deal with the science at hand,  
18 including all of -- when there is limited, but very  
19 important information available. Thanks to all, and  
20 the meeting is now adjourned.

21 (Whereupon, at 2:43 p.m., the Advisory  
22 Committee meeting was concluded.)

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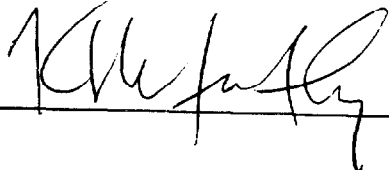
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