some comments about it, but certainly we are interested in hearing basically what you have to say.

But ultimately when there is sufficient interest in the pharmaceutical industry, we need to bring these questions to public discussion. We must also admit the following: that there is growing interest in gaining information about the usefulness of drugs in resistant indications. Doing this requires the commitment of resources on the part of the pharmaceutical industry. If there are no incentives whatsoever available at the end of the day for that type of commitment, then the likelihood of getting this information will be less than might otherwise be the case.

DR. RELLER: Please.

DR. DANNER: I think we're all agreed that the amount of data in actual resistant isolates is relatively small. So deciding whether the indication or changing the label makes sense is based on two things: one, that the overall resistance to Levaquin is very low; and the other, that Levaquin resistance and penicillin resistance are completely independent.

And so because I'm fairly ignorant in statistics, I wanted to ask our statistician whether we saw enough data today to conclusively say that they

are absolutely independent, and then ask the committee if they're independent today.

I mean I know they're independent mechanisms, but that doesn't mean genetically in clones of bacteria that they will necessarily be independent or stay independent.

So once this indication goes in, if they don't stay independent is that a problem?

DR. MURRAY: Resistances never stay independent. They can be totally different mechanisms, totally different everything. Once plasma mediated one chromosomal like ciprofloxacin resistant and MRSA, and they eventually come together.

DR. DANNER: Right.

DR. MURRAY: So in some instances, in this case you could think well in an HIV population which has high risk for penicillin resistant pneumococci probably have a lot of fluoroquinolone resistance. So you'd think they could come together independently if for no other reason than a fluoroquinolone gets used more often in the future because of that indication.

DR. DANNER: Well, yeah. That's sort of my point. I mean, in other words, if this goes into the label and four years from now it's no longer independent, i.e., that penicillin resistant organisms

also tend to be fluoroquinolone resistant and, therefore, fluoroquinolones and Levaquin specifically would not be a good drug to use if you know you had penicillin resistance, then it kind of makes the labeling incorrect over time.

DR. MURRAY: Yeah, but that's also true for every other antibiotic. I mean, resistance always develops so far. I mean you have to take it -- to me I think the caveat is we could say that about everything, every single drug that comes forth. I think most of us would agree there will eventually be resistance to everything.

But I'm sorry. You asked her the question. So I should shut up.

DR. DANNER: Yeah. Well, have we seen enough information with tests of independence to know that this is really independent?

DR. O'FALLON: No. You know, this is not very much information. I'm very aware of the fact that -- I mean it came through loud and clear -- that the company worked very, very hard to find these cases, and they were very, very rare, but they don't carry much information. That's the problem.

DR. MURRAY: He's asking about the resistances and there are huge numbers of isolates

that have been examined, thousands and thousands of isolates that Dr. Whitney told us about that have been examined. That's a huge database. That's separate from the resistance.

In the cases that you're talking about, I think you asked the question about the resistance per se.

DR. DANNER: Well, yeah, and the independence. So you could potentially look at, you know, any isolate, all the isolates you have and not necessarily just things that were in their studies and, say, do a statistical test. You would have to tell me which one, but say that there's absolutely no associationbetweenpenicillin resistance and Levaquin resistance.

I mean, did we --

DR. O'FALLON: Okay.

DR. DANNER: Has that been done or looked at?

DR. O'FALLON: That part. Okay.

DR. DANNER: Because we do have very few cases, but if they are completely independent, then that would say, well, the small sample we have may be large enough to make an overall generalization because the resistances are completely independent.

I mean isn't that one of the things that was decided on when this was discussed in the previous meeting, that independence was important?

DR. GOLDBERGER: Actually, if the company has a slide available from their background package of Table 11.2, it may address this issue since there was a considerably greater amount of information, as Dr. Murray just alluded to.

In that case it looks like there are, if I'm reading this correctly, some 4,000 isolates altogether that were looked at in terms of penicillin susceptibility, and then levofloxacin susceptibility, and there appears on the surface to be no difference in the pattern of levofloxacin susceptibility across the board regardless of penicillin, but I don't know if the company has a slide to put that up.

It's page 9 of the Trust data, I believe.

DR. MURRAY: I guess, Bob, biologically I'm convinced genetically that they are separate. They never transfer together, but I also would predict that in the future you will have -- the two independent things will overlap at some point, and that's certainly been true with other resistances that can be completely independent genetically.

And the phraseology I use is usually

resistance begets resistance or birds of a feather flock together, and that does tend to occur for perhaps population treatment basis, but not mechanisticallybybiochemicalmechanism or by genetic co-transfer, either one.

DR. SOPER: I guess I'm not so concerned about whether these end up coming together four years down hence because then there'll be a recognition that penicillin resistance is associated with levofloxacin resistance and the drug won't be used.

But as far as changing the labeling, I don't see a problem with what's proposed from that perspective. Maybe I've said what's already been said in another way.

DR. DANNER: Would the label then be changed again if they did associate with each other?

DR. GOLDBERGER: It certainly could be. I think that if you look, again -- I haven't had a chance to go through the questions, but it's all right. We can do it in a piecemeal fashion. It's just as good -- we asked in Question 2: do you have any recommendations regarding Phase 4 studies or data collection that the applicant could be requested to perform?

And data collection could, in fact, be an

ongoing targeted surveillance program to insure that we keep getting this type of information to look at the patterns as to what is going on.

On occasion, I mean, a lack of surveillance information sometimes has been a problem. One then has to negotiate with the company about this issue in terms of potentially changing the label, but that is possible to do, and there are, in fact, within the agency some initiatives underway about trying to do this more effectively on an ongoing basis.

But one of the keys is to insure that everybody's comfortable with the data that exists and what data might be used.

DR. DANNER: Well, I mean, just to clarify, the issue of independence allows you -- if they really are truly independent -- it allows you to extrapolate a little bit from the penicillin resistant isolates and say that, you know, Levaquin is very effective against pneumococcus. You have a large experience with that, and because Levaquin effectiveness doesn't associated in any way with penicillin resistance, it allows you to take this small group and kind of feel more comfortable because there's this much larger data set that should reflect the same thing in penicillin resistance or penicillin

sensitivity.

DR. GOLDBERGER: Well, I think probably our view would be if we were to ask -- and, again, it's based in part on the recommendations you make here today -- if we were to ask for surveillance because of concerns as Dr. Murray raised that over time one is always concerned that resistances may become linked, and that may become more and more of a problem, we would ask for as well not just penicillin patterns, but we would also ask for them to determine the levofloxacin susceptibility of the isolates.

I think the only way to be comfortable that there is not a change in what happens over time is to measure this on an ongoing basis.

DR. BUSH: We have some slides that I can show that demonstrate this. We have the data from the Trust studies showing the apparent lack -- yes, right.

We have one set of data showing the apparent lack of -- okay. There it is. Again, we're looking at large numbers of isolates here. Overall there are over 16,000 isolates that have been examined, and we have shown that there at this time appears to be no linkage between penicillin susceptibility and levofloxacin susceptibility.

In addition, what we have data on are the

25 levofloxacin resistant isolates that were identified in the 1998-'99 respiratory season, and can you go to Slide 336? Because I understand that there appears to be a question about cross-resistance here.

And if we look at those isolates that were resistant in the last respiratory season, there were 25 isolates that were resistant to levofloxacin. Of these, there was no apparent linkage to penicillin resistance. In fact, if anything, we had more that were susceptible in intermediate to penicillin.

Macrolide resistance was not linked. Trimetheprim sulfa was rather random throughout these 25 isolates.

So at this time we aren't seeking linkage. I agree that at some point we probably will be seeing super bugs that have resistance to everything because this happens with every organism, and I think Streptococcus pneumoniae probably in the long run will not be immune to this.

But at the present time we are not seeing cross-resistances. We are planning to continue to monitor. That is certainly a major concern of ours. It is something that we are committed to doing. We are planning to expand this not only in the United States, but also worldwide so that our monitoring will

continue.

Certainly we are veryinterestedin seeing whether we willbeginto see greater cross-resistance.

DR. RELLER: Thank you, Dr. Bush.

The reason for asking these questions is to clarify before voting on the questions, is to attempt to address the ripeness issue that Dr. Goldberger referred to, and not to skirt it, but at the same time to be very clear about the message that we're trying to send.

And I'd like for people to recall the remarks made by Dr. Bell earlier. It seems to me that the strongest message that's come across throughout this, and it's been stated repeatedly: no linkage currently; different mechanisms of resistance.

The failures in levofloxacin treated patients were all in patients with susceptible strains, penicillin susceptible strains. There appear to be no evidence that it makes any difference.

So, I mean, one can't have it both ways. If there's no linkage, there's no connection, there are different mechanisms of resistance, you get failures in susceptible strains and you get successes in resistant strains, and the drugs that are currently used according to recommended guidelines as regards

beta lactems, namely, that there is little or no evidence that in community-acquired pneumonia caused by strains of intermediate susceptibility or even at two micrograms per mL there's any difference in efficacy, and although the numbers were minuscule, the data presented here from the comparative trials didn't change that.

That's what the medical letter recommends. That's what the NCCLS stated in their next edition, that those strains at .125 to one.

Now, if there be no connection, that's why I think it's so important to clarify this because if the Question 1 is the same as the package insert question, then, in fact, what the package insert is doing is linking, implying that somehow efficacy may be linked or not linked with penicillin intermediate or susceptible strains, and all of the evidence suggests it has nothing to do with it.

And the statement is made that we have to look in the future, that susceptible to levofloxacin and efficacy, which has been demonstrated, may not hold up in perpetuity.

So I don't think that the questions and the package insert necessarily go together. In fact, I think you could argue that they are quite different

ways of looking at this issue.

Dr. Goldberger, have I made the point clear so that we know what we're voting on?

DR. GOLDBERGER: Well, I think that, you know, I'm not sure I necessarily follow your logic. I think that realistically what we're basically asking is that the company would like to include the words "penicillin resistant Streptococcuspneumoniae" in the label. Arguably we could have said that there's no issue with doing this. They could do this automatically because people have talked about there is no linkage and, therefore, that's not an issue.

And you could have just said why can't you just put it in there as long as there's no linkage. Then the issue would be, first of all, assuring ourselves that the issue of linkage was correct now, and then some means of insuring that that would stay that way in the future.

From our perspective, however, and I think there was support a year ago at the committee, there were concerns, however, that even if a linkage itself does not exist, that patients who have infections due to penicillin resistant Strep. pneumoniae may in other ways be different than patients who have infections with penicillin susceptible Strep. pneumoniae. They

may have different underlying diseases. They may have been on multiple courses of antibiotics. They may have other things that may influence how, therefore, they need to be treated.

So it was our view that clinical data was an important component of this. The question is realistically how much clinical data. I mean, that's basically the way we looked at it.

In other words, to put this claim in the label, we would like to see some clinical data, but as far as linkage or not, I think that I'm not sure. I think it's important, but I don't follow your argument that the two things are contradictory. I just I just don't follow that.

DR. RELLER: Well, I think they're different questions, and I'll be very direct because we need to move on with the questions and then let Dr. Murray speak.

For example, Question 1, I could envision someone saying that -- or the data that it's effective in penicillin resistant pneumococci, meaning two micrograms or more, and you've got 14 cases, that people could say the data are not sufficient to make that statement.

One could say that bacteremic or not,

levofloxacin works for community acquired pneumonia where you know that there's a pneumococcus present without regard to anything other than susceptibility to levofloxacin, that people could vote yes on that.

No in one and yes on the other, that is, by implication that it includes everything whether resistance or not because there's no relationship between resistance or intermediate.

DR. GOLDBERGER: Well, in essence, that actually gets to the heart of what we're asking you. We are asking for you to look at the totality of the data that exists, including the issue of the preclinical data that has been presented, the PK/PD data, and the information that's been presented in penicillin susceptible pneumococcal infections, plus the information that has been presented on the linkage, and using the totality of the information state whether the amount of data is sufficient that that line be included in the label.

So in essence, we are asking for you to consider all the pieces of information together and whether that is a sufficient package.

DR. RELLER: Okay. Dr. Murray.

DR. MURRAY: Actually one small technical question, and then I have some comments I'd like to

make.

Were the penicillin susceptibilities redone in a central lab or were they done on site? So they're redone in a central lab so that we don't have to worry about the issue of them coming from a single site, not knowing how to do the susceptibilities?

Okay. Then I think the problem, I think, that faced me -- thank you -- was there are two issues here. One is do we think it works, and the other issue is deep in our little hearts are we worried that if we say yes and it gets used even more than it is right now, that we're going to elicit more resistance.

And we're not really being asked to address that second issue in the first question. I'm not sure if we should be or not.

So the way I thought about it is --

DR. GOLDBERGER: Could I just, before you continue --

DR. MURRAY: Yeah.

DR. GOLDBERGER: -- traditionally when we talk about the issue of safety and efficacy, the traditional issue about safety is safety specific toxicities in the patient population and question. It is at the discretion of the committee whether, for instance, you want to consider broader safety or

public health issues. We did not specifically address those in our question because this option exists for you to discuss it, and in fact, as we expected, you know, it has already come up.

But you can if you wish address that on balance.

DR. MURRAY: Right, but I don't have to keep in the back of my mind to answer Question 1. I can save that for Question 2 that you've asked.

But if you look at the sentence does it work in pneumococcal disease, it looks spectacular actually if you look at it versus comparator. It works very well.

Would it meet the ten percent rule? Not quite, but it would meet the ten resistant isolates, and it would come close to meeting the ten percent rule probably or the ten percent idea for the intermediates. It has all of the right animal model pharmacokinetic data.

The company has, I think, read exactly what we wrote last year and went down and done everything we said we would want to see before approving something for a resistant organism. so I'll have an easier issue addressing number one.

I do, of course, in the back of my mind

worry as somebody that studies resistance. I worry a lot about eliciting more resistance, and then thinking about Carl asked the question earlier, is this going to be like -- are the fluoroquinolones going to mimic penicillin against pneumococci or is resistance going to be more rapid in developing?

We've had 15 years -- I didn't even realize that -- of a fluoroquinolone out there in the market, ciprofloxacin, that's been used a good bit or naroxyn that's been used to a certain extent. We've had 15 years. There's 100 million prescriptions did I hear?

I'm sure resistance is going to develop, and I wish we could address it in some way, but there's already a huge amount of use out there, and it looks like it's going to be relatively slow in developing because it's not more of a problem in 1999 than it is.

So I think I could address some of those issues separately, but I would likely when it comes to the vote have to separate those issues in my mind when making my final analysis of efficacy.

DR. RELLER: I think it's time for a vote. Yes or no, number one: are the data sufficient to demonstrate that levofloxacin is safe and effective

for the community-acquired pneumonia caused by penicillin resistant, two micrograms or more per mL, Streptococcus pneumoniae?

Dr. Murray?

DR. MURRAY: Yes. I think the data are sufficient.

DR. RELLER: Dr. O'Fallon?

DR. O'FALLON: I feel like I came into the middle of a game without know what the rules were, okay? So I really don't understand this well enough to make a vote. So I'm going to vote --

DR. RELLER: Pass?

DR. O'FALLON: -- pass.

DR. RELLER: Keith.

DR. RODVOLD: I agree. I think it is with one caveat though. As long as the dosages that currently are being proposed at 500 the MICs for levofloxacin is two or less, which is their sensitive break point.

If you move up to intermediate and above, those kinetics start to fall apart, and you might get questionable, and that means then the dose needs change. So currently, yes.

DR. RELLER: Dr. Christie?

DR. CHRISTIE-SAMUELS: I say yes with one

caveat for the labeling. Would the committee consider levofloxacin in the labeling for children with pneumococcal pneumonias and empyemas?

I believe this is still a safer and more effective alternative than the eventual need for a thoracotomy, drainage procedures, and pleural decortication for these ill children who have pen. resistant and pen. susceptible severe necrotizing pneumococcal pneumonias and pleural empyemas.

Thank you.

DR. RELLER: Dr. Soper.

DR. SOPER: Yes.

DR. RELLER: Danner?

DR. DANNER: Yes.

DR. PARSONNET: Yes.

DR. NORDEN: Yes.

DR. RELLER: Those are the voting members of the committee, and my vote is yes. MY qualifications will come later.

Okay. If the answer is yes, are there any caveats about its use that you would recommend to be included? Should any mention of PISP be made in the indications and usage section?

DR. NORDEN: Yes.

DR. RELLER: We'll go the other way

around. Carl.

DR. NORDEN: I have a couple of caveats. First of all, I think if you're going to put this in the label it needs to be stated that penicillin resistance can only be determined by susceptibility testing, which will not be available at the time the patient is first seen, as long as we're going to say what penicillin resistance is.

The second caveat would be that I think it should say that other antibiotics are probably equally effective for penicillin intermediate resistant pneumococcus based on pharmacokinetic data and sensitivity data, or we should leave penicillin intermediate sensitivity out of the label completely because I don't think that's our clinical problem, not for pneumococcal pneumonia. For meningitis, absolutely, but not for pneumonia.

DR. GOLDBERGER: Dr. Reller, can I make just a comment about the PISP?

DR. RELLER: Yes.

DR. GOLDBERGER: And that is that the company has specifically requested it, and we felt it was, you know, therefore, appropriate to give committee members a chance to talk about this.

I think that our own perspective is,

frankly, that we do have some reservations about this, but we think it is appropriate to have, you know, an open discussion.

In particular, if issues about resistance are to be included in the label, we think that -- and, you know, there's already been a little bit of comment just now about it -- we think that there ought to be some linkage to the fact that penicillin intermediate Strep. pneumoniae is, for instance, associated with a poorer outcome to penicillin because that is the presumption that many people reading the label would have.

So as you think about this, that would be one way to look at it. If we believed, for instance that it did make a difference, then I think, you know, it may very well be appropriate to make a statement.

If we think, however, that penicillin is still really the choice there, then our own perspective would be that that probably should not be in the label. However, you know, the company requested it, and we feel it's an important scientific issue that needs to have some discussion.

But that's the genesis of the specific nature of that as part of Question 1.

DR. RELLER: We will go around to all of

the committee members. We don't have a specific yes or no vote on Part 2(b). So we'll see what each person has to say.

And, Dr. Goldberger, can we formulate for your utility at the end of discussion, if it seems appropriate, on any specific measures to get a vote so that you get a sense of what people really think about, how strongly they feel about a particular specific issue?

DR. GOLDBERGER: Yes. (a) You are in charge, Dr. Reller.

DR. RELLER: Okay.

DR. GOLDBERGER: (b) It's often useful to have a sense of the strength of the committee's view on something.

DR. RELLER: Dr. Parsonnet.

DR. PARSONNET: I think PISP should not be in the recommendations. I think saying that it works for penicillin resistant strains already implies that it will work for penicillin intermediate strains, and including it, I think, would only serve to get people to use it more than they might otherwise, and use it in preference to antibiotics that have not yet had that as an indication.

And then I had a second question, which is

just a question for the FDA, is how the advertisements by the company are regulated, whether we have any -- those are two separate issues, whether when we do this approval we're sort of saying they can publicize this drug in any way or whether there are FDA requirements in addition above and beyond what these indications actually say.

DR. GOLDBERGER: First of all, there are certain options currently, and this is still under litigation about the ability to promote off label use regardless in fact of whether you have the indication.

Leaving that aside, however, for a second, the general rule is fair balance, that the statements in the labeling should not be taken out of context. If, for instance, one felt that caveats were important about how the drug should be used, what testing, et cetera, then the most effective way to insure that that material is included in the promotional material is to insure that it is also included in product labeling, and that, in essence, is the genesis of our question.

For instance, if you say it should be used only after testing, should be used in patients who are suspected to be at higher risk, although it would be nice to have some data about that, but whatever, that

information then we would expect would be in the promotional material along with the indication.

So it's important to give us a sense -- YOU don't have to give us the exact wording, obviously, in the label -- of the concerns that you would have that ought to be included so that there is fair balance and that those physicians who read the label or the promotional material will have a more complete picture of the situation.

DR. RELLER: What we'll do, Dr. Bell, unless you have to leave, is go around the committee members and the hear other comments, which we would welcome, want to hear.

My view on this is that it is a mistake to include any alteration in the label that has to do with intermediate strains or even resistant strains. We didn't have any recommendations having to do with doing something differently for levofloxacin with regard to sulfamethoxazol, trimetheprim, erythromycin, clarithromycin, macrolide susceptibility, yes or no. With what we heard, the choice of levofloxacin and what is done with the guidelines for pneumonia do not have it based on whether or not the strain is -- without regard to the susceptibility of the strain, and there are no clinical data that supports that it

makes any difference.

So that if it's not a factor, then it seems to me it should not be mentioned because of the possibility, indeed, likely probability by someone of promoting this when it's not germane to whether or not the drug works,a nd the continuation of the drug has to do with clinical response and whether or not it turns out if there be an isolate, whether it's susceptible by standardized testing.

Dr. Danner.

DR. DANNER: Leave out PISP for the reasons stated.

DR. RELLER: Soper.

DR. SOPER: I look at this as just adding another microorganism like E. coli or moraxel (phonetic) or whatever because of the ripeness dogma, and that I agree with Barth that it probably really isn't necessary, but because of the issue of marketing and its linkage to what's in the package insert that this becomes an important issue.

And, therefore, I would just support putting it in exactly the way that it was presented to us.

DR. RELLER: Dr. Christie.

DR. CHRISTIE-SAMUELS: No, PISP shouldnot

be included in the label. I think there is already enough confusion trying to sort out PISP from PRSP without adding yet another category for family practitioners.

I wonder if maybe we should just say all pneumococcal strains.

DR. RELLER: Dr. Rodvold.

DR. RODVOLD: I agree that I would leave it out, but I'd leave it out for all of the reasons above, but also another reason is that I'd be concerned with another company coming along wanting to only go up to PIS and not to go all the way to resistance, and so now you'd leave companies with penicillin sensitive, penicillin intermediate, but not penicillin resistant, and others with penicillin resistant and penicillin sensitive.

So I would leave it out, and you've got to go all the way to the top of the bar.

The other caveats in this question is that I think someplace in the labeling or in the back of the insert with studies and things is that at this time with the data that's available, that you've got to spell out or tell them that the comparative arms were equivalent, and that's got to get across so that the prescriber realizes that this was no better in

this and that the comparative numbers were the same, you know, 100 percent efficacy in there.

And that encourages, to me, the industry, this company as well as others, to then want to do more trials to prove that they are superior in the future or to change that labeling in the future, but currently that that needs to be in there.

And my other comments previously about the MIC for levo. needs to be also spelled out because it's important at this time.

DR. RELLER: Dr. O'FAllon.

Dr. Murray.

DR. MURRAY: I thought it was fairly easy to answer the question. This is the real hard part, and I do worry a lot about over marketing, and if there was some way to get a caveat in there about other antibiotics still effective in a number of instances or concerns about overuse and emergence of resistance, I would welcome the company to try to work on something that would make us happy because I think the company hears what our concerns are.

I think the phraseology of effective against CAP caused by pneumococci regardless of penicillin susceptibility might be a nice one, even strains not susceptible to penicillin, which is just

getting even more vague since that includes both categories.

But I do worry about how it's phrased and the potential for promoting even more use.

DR. RELLER: Dr. Bell.

Thank you.

DR. BELL: Thank you so much. I just wanted to advocate for the judicious use of fluoroquinolones. It's not just a matter of worrying about pneumococci developing resistance. It's nice to hear that in Japan this hasn't apparently happened, but there are the other respiratory pathogens or gastrointestinal flora. Levaquin has an indication for urinary tract infection, for example, and you know, I don't know what the prevalence of E. coli resistance is now, but it's an issue for cipro., and so I mean, fluoroquinolones are very valuable drugs, and we just want to make sure they're used judiciously also.

I want to -- I didn't know until just now that the indication being proposed was not only for penicillin resistant, but alsopenicillinintermediate resistance, and to me, speaking personally, including an indication for penicillin intermediate resistance is really the opposite of the way we ought to be

going.

I mean, why would a drug receive an indication for penicillin intermediate resistant pneumonia when even penicillin works for that condition? I mean, I just find that in terms of the confusion being sewn it would go from bad to hopeless.

DR. RELLER: I think, Dr. Goldberger, you have a sense on 1(b).

DR. BURTON: Graham Burton. I just wondered if I could reassure the advisory committee that were this indication to be granted with greater or lesser wording as your deliberations carry on, and in conjunction with our colleagues at the FDA, that we are determined to promote or market this product sensibly and correctly. I'd just like to make that statement to you.

You've already heard that we're going to continue with the Trust studies looking at the emergence of resistance in the community, and should any information or flickers of concern arise there, we will bring that data to the attention of our colleagues at the FDA and proceed from there.

We want to do this scientifically and correctly.

In terms of use of antibiotics by the

prescribing community, yes, we are integral even now as we speak with educating and being a participant alongside the professional societies, alongside the institutions, and we would not propose to do anything there that would be at all unscientific or dare I suggest unscrupulous? You have our word on that.

Thank you.

DR. RELLER: In other package inserts where it affects safety and efficacy, there are specific susceptible or resistant issues that are mentioned, like with Streptococci and beta lactems not to be used for excluding methicillin resistant strains. To bring this to a full head and to be very explicit, I think we've danced around the issue. I would like to suggest that we have a committee expression, yes or no, of the exclusion of any qualifier having to do with Streptococcus pneumoniae and community acquired pneumonia.

So community acquired pneumonia having to do with -- this is a comment from the committee. It's only advisory to the FDA -- is what the committee's sense is having to do with the simple statement of community acquired pneumonia owing to Streptococcus pneumoniae, period.

Dr. Norden.

DR. NORDEN: That was what I suggested at the beginning, and Dr. Goldberger answered, I think, appropriately regarding ripeness and so on.

I would prefer not to change the label because I think the potential for damage or misuse or misinterpretation is great no matter what caveats we put in and because I think the present label is sufficient.

So that's my comment.

DR. RELLER: Dr. Parsonnet.

DR. PARSONNET: I would favor actually including some reference to pneumococcal resistance in the label, and I would favor doing it maybe somewhere along the lines of what Dr. Murray said, making it a little bit less directly, something along the lines that you said, but I think there are a lot of physicians out there who may be seeing resistant isolates and might like that sort of guidance in the label.

DR. RELLER: I think the label should refer to Streptococcus pneumoniae susceptible to levofloxacin are the target organisms when one has an organism, and the empirical treatment for appropriate according to guidelines is another issue altogether.

Dr. Danner.

DR. DANNER: I guess I don't object to adding the penicillin resistant to the label. I think Carl's right. It's sort of cleaner and it covers the universe of issues, the labeling, as it is, but on the other hand, I guess I don't know of any compelling reason that would say that, you know, this shouldn't be done, and there's certainly a lot of antibiotics coming along that are being developed specifically for resistant type organisms.

So maybe developing labeling for that kind of indication is something that needs to be done for these future things coming along.

DR. RELLER: Dr. Soper.

DR. SOPER: I agree that I don't think the label needs to be changed unless the company is handcuffed in marketing because of no label change. In order words, I would say why change the label, but the company should be allowed in their advertising to say that their antibiotic is effective for the treatment of this microorganism, much along the lines that Barth outlined.

So if we don't change the labeling, does that mean the company can't market along those lines or are we saying we're giving this company and all companies to follow the opportunity to market any way

they see fit?

DR. GOLDBERGER: I mean, leaving aside the pending litigation which I would not try to comment on, not the least of which because I really don't understand it completely, the issue is that if the company is to promote in the normal fashion and state, for instance that penicillin, you know, resistance -- that it is effective against penicillin resistance isolates or, to use Dr. Murray's language, regardless of penicillin susceptibility, we believe that that information should be in the product label if they are going to, in fact, promote that.

To promote that type of information without its being in the product label sets a variety of precedents which I think in the long run would not be a positive thing.

DR. SOPER: Okay. So if that's the case, then I would support changing the label.

DR. RELLER: Dr. Christie.

DR. CHRISTIE-SAMUELS: I guess I'd have to maintain my integrity and stick with the former comment that we should probably just say all Streptococcus pneumoniae, implying susceptible, resistant, intermediate, recognizing, of course, that there will always be the risk that the prescribing

community might overdo it.

DR. RELLER: Keith.

DR. RODVOLD: I think that they should change the labeling. I think that, you know, we've had several meetings about this, and they've followed what we've suggested to do and stepped up to the plate at this point, and it will affect them from what you said in the advertisement and being able to promote it.

So I think you do have to at this point move ahead if you believe in the data which we just voted on in the first part.

DR. RELLER: Dr. O'Fallon, any comment?

DR. O'FALLON: Well, on the basis of the first one and the vote to the first one, which was unanimous, I believe, and hearing the comments here I don't see how anyone can deny that, them to make the change.

DR. RELLER: Dr. Murray.

DR. MURRAY: Yeah, I like the either regardless of penicillin susceptibility or including penicillin nonsusceptible strains.

DR. RELLER: Question No. 2, do you have any recommendations regarding Phase 4 studies or data collection that the applicant should be requested to

perform?

Anything that we haven't covered, Julie?

DR. PARSONNET: I favor a lot of what's been mentioned before, which is continued surveillance over time to see what happens to the Levaquin's activity and to see whether it does start to correlate with penicillin sensitivity at the same time.

And I think there has to be some understanding that the label might change if those aspects of the therapy change.

DR. RELLER: Bob, anything you want to say about two?

DR. DANNER: I guess this may be part of two and part of three, but I guess I would repeat some of the earlier comments that it would be a very correct thing for the company to try to do studies of Levaquin in children, particularly with severe pneumococcus disease since there's a higher incidence of resistance, and studies in that population would be very helpful in terms of knowing how to use the drugs in those settings.

DR. RELLER: Dr. Christie, anything further to say on two?

DR. CHRISTIE-SAMUELS: I would have to advocate for children again. I believe studies should

be performed in health children who are hospitalized with community acquired pneumococcal pneumonia evidenced by a positive blood culture or positive pleural fluid, regardless of whether the organism is drug resistant or drug susceptible to whatever drug.

Thank you.

DR. RELLER: Dr. Murray.

DR. MURRAY: Not really, and I wouldn't want to say anything bad about children, but just to remind the commonly quoted phrase that the best thing that ever happened to preserve the life span of the fluoroquinolones was those beagle puppies, and the fact that the drug has not been out there in wide use in the pediatric day care center population, but I certainly think it needs to be and has to be studied in severe disease in children.

DR. RELLER: Question 3, do you have any recommendations for future clinical trials? Such recommendations might address, but not limited to issues of the supportive value of isolates from other body sites, usefulness of data from penicillin intermediate isolates.

We'll go in the reverse. Dr. Murray, any comment on three?

Dr. O'Fallon?

Rodvold?

Christie?

DR. CHRISTIE-SAMUELS: Clinical trials in children again.

Thank you.

DR. RELLER: Dr. Soper.

Danner.

Dr. Goldberger, Dr. Kweder, any closing remarks?

Yes, Dr. Christie.

DR. CHRISTIE-SAMUELS: Just one more. When we're looking at children, if we could somehow find out if the drug is concentrated in the pleural fluid, that would be good, too.

DR. RELLER: So in summary, I think we have a strong sense that this drug works for community acquired pneumonia without regard to susceptibility or resistance for pneumococci, and how best to handle that fortunately rests with the FDA.

Yes, Dr. Kweder.

DR. KWEDER: I just have one final comment. I want to thank you all for your deliberations. I think that this is something. The fact that we have had I think this probably brings us to three, maybe four advisory committee meetings where

this general area of discussion has been held, sort of serves to illustrate what a difficult topic or area this is to get your arms around from both scientific and a regulatory perspective.

Some of the things that you've touched on today fall into a general construct that we're grappling with at the agency that goes even beyond antibiotic resistance, which is a construct of risk management, and if we think about antibiotic resistance, both the treatment of patients with resistance organisms and the further burden of preventing the development of additional resistance, those all come under the broad heading of drug safety both for individual patients and the public health and risk management.

A lot of risk management not only involves risk assessment, what's the risk of future resistance, some of the things you've talked about today, but also how do we educate the public health professionals and consumers about how to manage that risk and prevent it from becoming greater.

Some of that from our standpoint comes in how we -- the language we choose for labels, where we choose to include things in labels and not, and so we've heard you today, and we really thank you for

your comments. I think sometimes you feel like they're just out there with few constraints around them, but they are very meaningful to us in application to what we need to do now with review of this NDA. So thanks.

And there will be more of that tomorrow.

DR. RELLER: We'll reconvene at eight o'clock in the morning.

(Whereupon, at 5:22 p.m., the meeting was adjourned, to reconvene at 8:30 a.m., Thursday, October 21, 1999.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: 67TH MEETING

Before: ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE

Date: OCTOBER 20, 1999

Place: SILVER SPRING, MARYLAND

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

irene gray

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**Look-See Concordance Report**

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UNIQUE WORDS: 3,809
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