from early phase trials, or are some of these from actual patients, and what are -- particularly, I ask in respect to data we heard yesterday where blood levels in sick patients, or in patients at least, were actually higher than in the Phase I and II studies, or Phase I studies? So, when we see 3.6 or 4.52 on day ten of multi-dose as a Cmax, what is that -- is that from patients, and, if not, do you have data from patients?

DR. SACKS: The results that I've presented, as far as I'm aware, are from Phase I and II studies, they are not from clinical trials. That's being concurred with.

DR. MURRAY: So, they are not data from lots of real live patients?

DR. SACKS: No.

ACTING CHAIRMAN RELLER: Dr. Soper.

DR. SOPER: Well, I can't say that I'm impressed with QTc intervals or whatever they are, which is a questionable hint of a possible significant measurement, but I am impressed about this 33-year old male who, an interesting use of words, tolerated the 400 milligram infusion to arrest 11 minutes later, and this was felt to be a vasovagal reaction. Does this imply that this isn't related to the drug, and can you

expand on this adverse cardiac output? It's on, I think it's your No. 16.

DR. KUBICE: I'm Dagmar Kubice, I'm a Clinical Pharmacologist from Bayer.

I happened to be on the ward when this happened, actually I was the treating physician, so what I can tell you is that this episode happened right after blood was withdrawn from an IV cannula, and that's something like a drop in heart rate that we'll see quite often afterwards as a vagal episode. But, this was very extreme.

DR. SOPER: So, this individual has a line in his arm, you are putting a needle into something which doesn't stick his skin and drawing out 10 ccs of blood, and you think that that is a vasovagal reaction in this case?

DR. KUBICE: Well, you see that, and I mean if you talk to other Phase I units, I mean, this, thank God it's not very often, but it happens, and it's when you are manipulating an IV cannula. That's a very strong vagal episode.

DR. DiMARCO: John DiMarco from Virginia. I'm an electrophysiologist, and I'd just like to comment on this, that since we started doing tilt tables in people with neurocardiac or vasovagal

syncope, or whatever you want to term it, it's really remarkable what you can see. I think the record at our lab is 57 seconds of asystole in somebody with recurrent syncope. And, in it's in somebody with a normal heart, I'm sure Jeremy or Joel have, you know, similar heart harrowing experiences, and yet these people recover.

The fact that they do get -- because they are in that situation they do get some CPR often, they do come back with an idioventricular rhythm, then a junctional rhythm, and that's just what we call neurocardiac syncope.

DR. RUSKIN: I would agree. I listened to this w thout the slightest bit of concern. It's a classic vasovagal reaction, and we see it in the cath lab and electrophysiology lab every day, just manipulating catheters with indwelling lines. So, I would have no concern about it being a drug-related proarrhythmic effect of any kind.

ACTING CHAIRMAN RELLER: Dr. Parsonnet.

DR. PARSONNET: I was just curious about whether you had any more information about the dizziness that seemed to be more apparent in the sponsor's product than in the comparator, and whether that was vertigo or whether it was lightheadedness.

DR. SACKS: I, myself, can't give a whole lot of clarity on that. It wasn't listed as vertigo, it was listed as dizziness, and I think that's probably the limit of my knowledge of the data. Perhaps, Bayer may have some additional comments on that.

DR. HOLLISTER: Alan Hollister. You know, one of the protocols that we conducted was the sinusitis, where we were doing antral taps, and I don't know about you, but I faint when somebody sticks a needle through my bone into my nasal sinus, too, and most of the episodes of dizziness were due -- occurred around those times or with blood drawing, but not all.

ACTING CHAIRMAN RELLER: Barbara.

DR. MURRAY: So, you don't think this is that frequently seen with other fluoroquinolones, CNS sort of symptomatology? I mean, you think this was episodic due to a particular intervention, the dizziness, or did you think that there was -- not that it's a significant drawback, but it certainly, with other fluoroquinolones there is that --

DR. SACKS: Correct. I think the answer in part is the fact that even the sinusitis studies were controlled, so, in fact, my sense is that there was an increased signal and it probably does relate to

the drugs. It did not come across from viewing the data that this was directly an arrhythmic effect, but certainly it did seem to be drug attributed.

DR. HOLLISTER: In the all adverse drug reaction group, there were uncontrolled sinusitis studies, that is, ones that the subjects only received the moxifloxacin. So, we don't have the comparative frequency there.

But, I agree with you that there are multiple causes of dizziness, and we certainly cannot rule out that this may be a fluoroquinolone effect.

ACTING CHAIRMAN RELLER: Dr. Temple.

DR. TEMPLE: Just to come back to the QT, I was left slightly confused by one of the discussions. Dr. Platt, I think, was asking whether the dose had been pushed enough to find out what the QT effect would be at relevant concentrations, because in the data relating QT prolongation to concentration relatively few people were up where you thought they ought to be.

Did I understand Dr. Morganroth and the company to be saying that their conclusion about what the true QT prolongation effect is comes from patients who were studied, several hundred of them anyway, at whatever their concentration -- at whatever their --

at approximately their Cmax, so whatever that was was what they reach, and that that was the nature of, that was the source of the six millisecond average response? I mean, is there a contradiction between those two, and is it resolved?

DR. PLATT: It sounds like a contradiction to me. I don't understand how people on therapy can have levels that are substantially lower than the Phase I normal volunteers.

DR. MORGANROTH: This is Joel Morganroth. I think there isn't a controversy. I think that Bob is right in the sense if you take single doses in healthy volunteers in a Phase I unit, what I don't think Bayer did is they pushed single doses high enough to reach steady state 400 milligram a day plasma concentrations steady state. Okay, so, well, I'll let them comment on the plasma levels, I'll just address the QT issue.

What I said before was, if you take whatever the relevant concentration is in patients at 400 milligrams a day in Phase III large clinical trials, in which they didn't measure any concentrations so we don't know what those concentrations are, but at that dose you get a mean of six milliseconds. And, when you compare big Phase III

trials with other drugs that have, let's say, 20 milliseconds in their clinical dose, the 20 milliseconds acts seemingly badly in marketing experience, if you will, where the smaller durations we don't have any data to suggest that they do or don't, frankly. There doesn't appear to be, from what we heard at the last presentation, that they do.

But, I'm not addressing plasma concentrations, so the real question, or an additional question, or another question is, how much can you rely on plasma concentrations to reflect QTc changes and what they did with single doses versus multiple doses. And, did they give enough of a multiple dose accelerated, you know, dosing schedule to see what the QT could do at 3x dose, 5x dose, et cetera, I don't think they have that data.

But, I can't answer the concentration issues, maybe Dr. Hollister can.

DR. HOLLISTER: We were very interested in just this problem, and do you have the slide number, carousel five, slide 61. In partial answer to your question, I took data from our crossover studies, where patients were treated with a single dose of moxifloxacin anywhere from one week to six weeks apart, in terms of wash out, and measured the change

in QT interval that they had with their first exposure and with their second exposure.

And, this is a plot that we know Dr. Temple likes. Okay, change in QT after the first and second exposure to moxifloxacin, the first exposure is plotted on the X axis, the second exposure on the Y axis, and although this slide is kind of small and doesn't project very well these are the axes here.

So, for instance, this person out here, first exposure to moxifloxacin had an increase in the corrected QT interval of 89 milliseconds. The second time, either one to six weeks later, had a decrease of 11 milliseconds. So, this, you know, kind of supports the whole concept that there is a great deal of intrinsic variability in the measurement, and what we are doing is, we are seeing a little bit of effect on top of that intrinsic variability.

If you look at the clustering of the dots, you know, ideally if there were no relationship between the first and the second exposure, in terms of the change in QT, you would have a scattergram that would be essentially a circle, but, in fact, that circle is displaced up this way about six milliseconds, I think.

DR. PLATT: That all sounds fine. It

seems to me, though, that the clinical data is giving a prolongation that is exactly what you saw with the single dose of 200 milligrams on Dr. Sacks' slide, and so either dose doesn't make -- serum concentration doesn't make a difference, or the mean concentration in your clinical trial group who had paired ECGs was on the order of what your volunteer population achieved with a single dose of 200 milligrams.

And so, that just sort of takes me back to Dr. Ruskin's question, do you have enough data on the clinically relevant concentrations that will be achieved when you leave the clinical trial environment?

DR. HOLLISTER: Well, I think the key is, the clinical trials were clinically successful, okay, at whatever concentration we achieved in those clinical trials. That concentration resulted in a QT change of about six milliseconds.

DR. PLATT: Fair enough. Hard to know where that will go, and if you believe Phase I data, it makes it just hard to understand.

I guess the other thing to keep in mind is, if there's that upward tilt, and some people achieve those higher concentrations, a very much larger fraction of those people will have more than 60

millisecond prolongations than two and a half percent. It might be 20 percent or 30 percent who have 60 millisecond prolongations if, in fact, the average is on the order of ten or 20.

DR. HOLLISTER: Well, I agree, and I think that's sort of the essence of the issue, is, you know, if someone achieves a very high blood concentration of a drug, and that's why we tried to emphasize that, you know, here's a drug that doesn't have any interactions that result in drug accumulation, here's a drug that doesn't have any elimination issues that result in drug accumulation. That, I think, is how we factor the pharmacokinetics of this drug into the risk equation.

DR. RUSKIN: Just a point of clarification in reference to Dr. Platt's comment. I didn't -- if I implied that I didn't think the data from the clinical trials was relevant, I certainly didn't mean to do so. I think that that is the only relevant data, and it's what we have to base our assessment on.

What I did say was that in the higher risk subsets, which are very hard to study, people with congenital long QT syndrome, people with phenotypically normal EKGs, and genetic abnormalities of K channel metabolism, people on concomitant Class

3 anti-arrhythmic agents, those are the ones that we worry about, and that's the small subset in whom we have no data, and that was really the only point I was trying to make.

I think the clinical data that you have is very important, and it probably applies to 99 percent of the patients who are going to be treated with the drug.

DR. SACKS: I was just asked to project this back-up slide, which shows very small numbers of patients, it's the information that we have available, looking at much higher serum concentrations based a small study of intravenous infusions at different infusion rates. And, perhaps, that will give you some idea of the very small amount of data that we do have to show what happens when you give higher doses to the change in the QTc interval on the Y axis.

ACTING CHAIRMAN RELLER: Dr. Temple.

DR. TEMPLE: Actually, in a carefully -- very, very carefully controlled environment, youI perhaps, could study the interaction of drugs that prolong the QT interval that are known to in your drug. YOU know, people have -- even people who work for the FDA have carried out studies of interfering with terfenadine metabolism and noting what happened,

which was impressive. That might be a piece of information that would be useful.

To my knowledge, Jeremy, I don't know that there is anything quite like that. People assume that if you add this drug sotalol it will be a problem, but it may be they are working the same --

UNIDENTIFIED SPEAKER: It was in dogs.

DR. TEMPLE: Is it? Well, and maybe that's a clue, but you can form hypotheses in which if you've already blocked the system you don't do much by adding a rather poor blocker to a big blocker. So, you don't really know until you look, but maybe the dog models have told the answer to that, I don't know.

DR. RUSKIN: Unfortunately, your hypothesis has not been borne out by clinical experience, and that is that the effects of most of these agents appear to be additive.

But, you are right, it's something that could be tested on an in-patient basis if someone wanted to do the trial. There's certainly a lot of people getting sotalol initiated on an in-patient basis. So, it's conceivable that one could do that, but absent those data I think one would have to be very cautious about labeling.

DR. PLATT: One last question, Dr. Sacks,

how do you interpret the hypokalemia data?

DR. SACKS: I think the best I can do is just share it with you. I think there's definitely a difference in the incidence of significant prolongations inpatients who are hypokalemic compared to normokalemic, and it's a concern that I raise, a genuine concern that I do raise.

ACTING CHAIRMAN RELLER: Dr. Battinelli.

DR. BATTINELLI: I just wanted to ask Dr. Ruskin a question, and then maybe make one observation, and that is that the majority of the people that are going to be prescribing this antibiotic do not have Dr. Ruskin and some of the others' background. And, I don't think Dr. Ruskin is going to be prescribing this a lot in his office, maybe he will based on what he learned here.

And so, as a clinician who is not going to look at the QTc each time the prescription is going to be written, and whose patients will be some of Dr. Ruskin's and some of others on some of these other agents, I'm also very concerned at least about how the label is currently being asked to be arranged.

The other part is that Dr. Ruskin has been referring to the 1A and 3 anti-arrhythmics, but I seem just to infer from his comments about cisapride that

there's just as much concern with that drug as with the anti-arrhythmics.

DR. RUSKIN: Well, the second question is either than the first, and I would agree that I would have concern about any drug concomitant use of this agent or any other Ikr blocker with any other drug that belongs in QT interval, absent convincing data that it was safe.

The first question is much harder to ask, and it comes up in reference to anti-arrhythmics and all sorts of other agents that have far more profound effects than this drug, and that is how does one factor in the way in which drugs will ultimately be used by the medical community, and I certainly don't have an answer to that. I think that's the $64.00 question.

The data on this drug would appear to be reasonably comforting with regard to the fact that there are no signals, and most importantly that there are no interactions with the cyp 450 system, so that it's unlikely that there will be a lot of catastrophes from metabolic interactions with drugs that interfere with the metabolism and excretion of the drug.

If that were present, I think the concern would be much, much higher, but my major concerns

relate to precisely what you described, and that is use with other drugs that prolong the QT, and then that very rare undetected individual, who either has the long QT syndrome at baseline, or what we now know to be a phenotypically normal EKG, but a genetic abnormality of K channels that make them particularly susceptible. And, that ends up being some sort of a risk benefit assessment, and how you do that is not easy in this situation. The drug appears to be effective. I initially thought that it looked pretty good again pen resistant Strep. pneumoniae. I thought that that would be, perhaps, a major factor in its favor, and I was impressed with the mortality data, although I must admit I'm a bit confused about that now that I've seen Dr. Sacks' analysis.

So, I think it's very hard to know exactly how you balance these things, but I can tell you that if we were to eliminate all drugs that affect the QT interval we would have a profound impact on our pharmacologic armamentariumincardiology, psychiatry, infectious disease and most other areas. The more we look, the more drugs we find have these effects, and each drug that comes up gets held to a higher and higher standard. It gets more and more difficult to evaluate and to make these assessments.

So, the bottom line is, I don't have a simple answer for you, and you can't control practice, you just have to label things as intelligently as possible, and I think do very careful post marking surveillance. I should add that at least I know Dr. Morganroth, and I'm aware of quite a few cases of Torsade with sparfloxacin that have been reported in Europe. So, I know you've got one case here, but there are a lot more than that that are now reported outside this country, and I think very, very careful post marking surveillance would be critical here.

ACTING CHAIRMAN RELLER: Dr. Ruskin, relative to the possible additive component with cisapride, the class 1A3 anti-arrhythmic agents, compared with those added compounds and the rare congenital hereditary aberrations where does hypokalemia figure in, which would be encountered much more commonly than at least some of the others, in terms of --

DR. RUSKIN: Well, it's probably a very important factor, along with bradycardia. Certainly, we know that Ikr blockers, for example, Ikr is really most active at slow heart rates, and bradycardia is a very important predisposing factor to Torsade.

One of the ways of preventing Torsade,

even with a very potent Ikr blocker, is just to drive the heart rate up.

Potassium is in a similar category, and that is significant hypokalemia is a very powerful stimulus to Torsade in the setting of a drug which blocks Ikr. So, I think it is a major issue.

How to quantify it, how to put it into the equation, is something I can't even begin to figure out how to do. It certainly ought to be in labeling, but how that translates into clinical practice is a very difficult issue.

ACTING CHAIRMAN RELLER: To follow up on that, and this would be addressed to you, Dr. Hollister and Dr. Morganroth, any or all, in listening to the discussions I have the impression that it's very difficult, it, perhaps, may be easier to delineate what's real, that is related to the drug versus what is risk, but you, I believe, suggested that though the risk may be difficult to quantitate that the comparator gives possibly important information also.

So, in that 1ight, is there an important difference in the QTc measurements with this agent and one of the commonly used comparators, the six milliseconds and the two milliseconds for

clarithromycin, and fuse that question with the experience here on the QTc changes with this agent versus the comparator in the presence of normal kalemia and hypokalemia, given what you said about hypokalemia?

DR. RUSKIN: That's a long question.

ACTING CHAIRMAN RELLER: But, you see where I'm going, or asking, is there a difference between these agents, and does hypokalemia bring it out, and does it bring it up to where it's something that's important?

DR. RUSKIN: I think the simplest answer I can give you is that the numbers are too small to answer that question. I just don't think you know. I think you know -- all you know is that there is some theoretical risk here that you can't get your arms around. You know that clearly there under some circumstances in some small subsets of patients, there will be some risk for trouble with this agent. Nobody can tell you what that incidence will be, except that it will be low. And, one has to balance what is likely a very low risk against the potential benefits of the agent.

With regard to comparators, it would appear that this looks better than sparfloxacin and

probably not quite as good as most of the comparators, although certainly the differences are rather small, and I think that's about as far as you can take it. I think that those numbers are interesting, but the numbers are so small that I can't make any useful conclusions from them.

ACTING CHAIRMAN RELLER: The reason I'm asking these specific questions is, in terms of fairness what constraints, restrictions, warnings, things that are pointed out of having them relative to the possible or probably relative risk, that we don't know what it is.

DR. RUSKIN: Well, some of your responses I think, or some of what you do is based on data and some of it is based on what you know about a drug being an Ikr blocker, and you have to do the best with both of those. And, in this situation, from my perspective, it would involve contraindicating the drug with concomitant agents that prolong the QT interval, contraindicating its use in people with known QT prolongation, and making very clear statements about the additive risks of hypokalemia and bradycardia and other factors which predispose to Torsade in the setting of an Ikr blocker, which this is. I think that's all you know.

There is no way to take it a lot further than that, that I'm aware of. And, one could argue that that should be applied to several of the drugs that are already out there.

ACTING CHAIRMAN RZLLER: Thank you, that's very helpful.

Dr. Temple.

DR. TEMPLE: I thought you were also posing the question of whether it's fair to discover something and label a recent drug with harsh labeling restrictions when there are some old drugs around that look like they might be just as much of a problem and they are not labeled yet. This comes up all the time. It's a concomitant of learning things, and as a general matter we have taken the position that we need to label the new drug the way it is properly labeled, and we'll get back to the others and try to change them, too.

But, people observe to us that quinidine, a probably more dangerous anti-arrhythmic than many of the newer ones, had relatively light weight labeling compared to some of the newer drugs, and we eventually went back and heavied it up. But, that comes up all the time, you sort of have to do what you have to do, and then go back and get them, perhaps, with a greater

urgency than we've always done it.

ACTING CHAIRMAN RELLER: It's the intention of question four, I believe, to make sure that we get a sense from the voting members of the committee to be transmitted for your final consideration.

At this point, I would like to turn to Dr. Mark Goldberger, to focus things for us so that we can address expeditiously the questions, while we have a full quorum.

DR. GOLDBERGER: Thank you, and we have posed four questions for the panel.

The first, has moxifloxacin been shown to be safe and effective for the treatment of uncomplicated skin and skin structure infections, community acquired pneumonia, acute exacerbation of chronic bronchitis, and acute maxillary cellulitis. We've listed the indications separately, first of all, because one needs to obviously look at the efficacy for each indication separately, and also because it is reasonable at times to consider looking at safety in the light of the amount of efficacy achieved and the indication in question.

If the answer is no for one or more indications, what additional information would be

required? If the answer is yes for any or a11 of the indications, are there any caveats regarding its use that you would recommend be included in the product labeling?

As part of your discussion of the community acquired pneumonia indication, and I would also add to this the sinusitis indication, please address the applicant's request that the indications and usage include PRSP. Should you recommend inclusion of PRSP, should any mention also be made of PISP in this section? Obviously, this is an issue that was addressed in part yesterday with a different product as well.

If the answer to question one is yes for one or more indications, do you believe that the labeling proposed by the firm regarding the prolongation of the QT interval produced by moxifloxacin is adequate? If not, what modifications would you suggest? And, again, we've heard a lot of comments about this already, a variety of concerns. It's important to do the best you can to be as specific as you can with this regard for our further discussions with the company. Obviously, this is the type of information that could ultimately affect other products as well, but as Dr. Temple said a moment ago,

a journey of a 1,000 miles basically begins with the first step, and this is, you know, probably the first place where we have sufficient data and the opportunity to get expert opinion about this issue.

If moxifloxacin is approved, do you have any recommendations regarding Phase IV studies or data collection that the applicant should be requested to perform? And, this can include any variety of issues, including looking at alternative doses in some of the indications if you believe that might be reasonable, additional types of surveillance data in terms of resistance, other issues in terms of looking at the QT prolongation, or other, for instance, safety issues.

And finally, the last question, and I guess we are focusing more on this last question for Dr. Ruskin and Dr. Morganroth, although obviously anyone who likes can participate, do you have any recommendations regarding the parameters, both qualitative and quantitative, that may be most useful in assessing the significance of QT prolongation caused by anti-infective products?

Now, what particularly obviously is a starting point, trying to distinguish basically cardiac and non-cardiac, and, obviously, anti-infective or non-cardiac drugs. This could obviously

have just been listed that way, but we don't feel it's appropriate to step over into other people's territory, we have enough problems with the anti-infective products. But, we would appreciate, we have gotten some advice, we would appreciate, for instance, whether there are certain screening tests early in development that might be very helpful in determining how much other data ought to be collected during the Phase III studies, or whether, regardless of early screening tests, a certain amount of EKG data should be collected on all drugs, on certain classes, et cetera. Whatever advice, and, again, you know, as specific as you are able to make it, would be very helpful. This would obviously apply both to new products and potentially to getting additional information on products that are already in the marketplace.

Thank you.

ACTING CHAIRMAN RELLER: In considering these questions, since the safety presentations and the discussion across all indications, I think it may be most efficient to address the efficacy components by indication and then to address the safety issues, because they are concentrated on questions two, three and four.

We are going to vote. We can discuss, if necessary, the members should not feel compelled to comment when something has already been stated, so what I would like to ask in sequence for the four requested indications, and we recognize that this is a perspective of the advisory committee presented to FDA for consideration.

The first question is, has moxifloxacin been shown to be effective for the treatment of uncomplicated skin and skin structure infections?

Dr. O'Fallon.

DR. O'FALLON: Yes, I thought, for all four.

ACTING CHAIRMAN RELLER: And, actually, you've made a further refinement. Let's have you vote on all the components all at one time, not as a package, but individually, and if there be -- Keith?

DR. RODVOLD: If I understand you, I'm voting on all four, but one by one?

ACTING CHAIRMAN RELLER: If you think that it's been shown to be effective for all four, say so. If there's something for which you think it has not been sufficiently -- there are sufficient data, point that out, so that Rhonda Stover, our Executive Secretary, can take a composite vote and break it down

into the individual indications.

DR. RODVOLD: For all four indications, I think the data proves that it's safe and effective.

ACTING CHAIRMAN RELLER: Efficacy.

Yes, Dr. Christie, your vote on efficacy for these four indications.

DR. CHRISTIE-SAMUELS: For efficacy, for uncomplicated skin and skin structure infections, the answer is yes. For community acquired pneumonia the answer is yes. However, I am not convinced that the data shows that there is efficacy for bacteremic pneumonia, nor am I convinced that the data is efficacious for patients who have drug resistant Strep. pneumo. I think the numbers were very small, and I think six to seven percent is probably not convincing for me.

For acute exacerbation of chronic bronchitis, the answer is yes for efficacy. For acute maxillary sinusitis the answer is yes for efficacy. However, again, back to drug resistant strains, the data presented by the drug manufacturers, I think that might not be very convincing also for drug resistant Strep. pneumo.

Thank you.

ACTING CHAIRMAN RELLER: Help refine, we

will come back to Dr. Christie, because we are going to address this in 1B, the issue of resistant and intermediate strains, in terms of susceptibility to penicillin, so that we will take your comments, keep them separate and go on for the general indication without regard to the subcomponents.

DR. CHRISTIE-SAMUELS: In general, the answer would be yes for all four.

ACTING CHAIRMAN RELLER: The specific indications, but without regard to the subcomponents of a particular organism.

DR. CHRISTIE-SAMUELS: Without regard to bacteremic pneumonia or drug resistant isolates.

ACTING CHAIRMAN RELLER: Dr. Soper.

DR. SOPER: Yes, for all four.

ACTING CHAIRMAN RELLER: Bob?

DR. DANNER: Yes, for all four.

ACTING CHAIRMAN RELLER: Yes, all four.

DR. PARSONNET: Yes, for all four.

DR. ARCHER: Yes, for all four.

DR. MORGANROTH: Yes, for all four.

DR. NORDEN: Yes, for all four.

ACTING CHAIRMAN RELLER: Thank you.

Now, we will tackle head on, and also in relation to the extensive discussions undertaken

yesterday of what our recommendations are to the agency regarding penicillin-resistant Streptococcus pneumoniae and penicillin intermediate Streptococcus pneumoniae.

Dr. Goldberger, would you like for us to handle those individually or together?

DR. GOLDBERGER: The penicillin resistant Strep. Pneumoniae?

ACTING CHAIRMAN RELLER: Those strains that have MICs above -- .125 or above to penicillin.

DR. GOLDBERGER: I suppose depending on what the committee thinks, you may want to just include them all together. I will leave that to your discretion, and to what the comments sound like.

ACTING CHAIRMAN RELLER: All right, we understand.

Dr. O'Fallon. Do you want me to start on the left side this time? That's all right, that's what we'll do.

Dr. Norden, did you vote on the last one?

DR. NORDEN: Oh, yeah.

ACTING CHAIRMAN RELLER: I thought so. Okay.

DR. NORDEN: I always vote.

I guess I'm with Dr. Christie on this, but

it bothers me because I think I'm not sure we're being consistent from yesterday. If you total it up there, the sinusitis and pneumonia cases based on Dr. Meyerhoff's review, there are 14 isolates, as I see it, which are resistant. I mean, my answer is very simple about intermediate, it shouldn't be included in any label, just as we did yesterday, but for the resistant there are 14 in the sinusitis and pneumonia, and there were 12 successes. And, my recollection is that yesterday we didn't have that many more resistant isolates either, although they were all in pneumonia. I am not convinced by this, and I'm going to vote no, but I do think I'm not sure I'm being very consistent.

DR. GOLDBERGER: There was a question we actually asked yesterday that no one commented on, probably because it was by that point 5:30, and that was about in future studies whether organisms from different body sites could be combined for information. No. one touched upon that. One of the differences between yesterday and today, as you pointed out, all the isolates were from community acquired pneumonia. Here they are from community acquired pneumonia and sinusitis, leaving aside the one from bronchitis. The question is, is can they be reasonably combined?

There may also be differences in the total body of pneumococcal experience with the product, which we haven't spent a huge amount of time talking about, which I think are probably different.

ACTING CHAIRMAN RELLER: Carl, just to recap the numbers, for those community acquired pneumococcal pneumonias, for which we are absolutely certain of the etiology, in the database that we are talking about today there are eight such patients in the highly resistant, 17 in the moderately resistant, versus the comparative numbers for yesterday's discussion of 14 and 44, so, roughly, the database is about a third as big for bacteremic pneumococcal pneumonia.

DR. NORDEN: Not bacteremic, just pneumococcal pneumonia.

ACTING CHAIRMAN RELLER: I'm talking about bacteremic.

DR. MURRAY: But, the bacteremias, none of them were penicillin resistant. There were about ten bacteremias, from what -- ten or 11, but she presented data on the seven, on the efficacy in bacteremia from seven of ten. But, if you are penicillin resistant, none of those were thought to be bacteremic.

So, I agree, we didn't have the body of

pneumococcal experience, in my opinion, we didn't have the 218 cases, we didn't have the number of penicillin resistant or intermediate, we didn't have the number of bacteremias within the penicillin resistant intermediate, and we didn't have data on the severity. We were told of 14 severe in the intermediate, four severe in the penicillin resistant group yesterday. We didn't see an animal model looking, although I assume it would be the same, of penicillin resistant versus penicillin susceptible pneumococcus showing equal efficacy with moxifloxacin.

So, whereas, based on pharmacodynamics I would think it should work, I didn't think we had the same body of literature, which is just what you said.

DR. NORDEN: I'm very comfortable with that, and Barbara has helped me, but I think that if we are not going to combine the studies, we are only going to talk about pneumonia, I think then my vote is much easier. I think eight isolates is not a lot, and we don't have the other information that we did have yesterday in terms of severity of bacteremia and so on, so I'm comfortable voting no.

I think that Dr. Goldberger's question is a legitimate one, though, about pooling for future and for, you know, other products or this product.

ACTING CHAIRMAN RELLER: The question we are addressing now is the database for strains that are less than fully susceptible to penicillin for community acquired pneumonia.

DR. NORDEN: I'll stay with the no vote.

ACTING CHAIRMAN RELLER: And, this is for intermediate and fully resistant strains.

DR. MURRAY Right, and I would agree with that also, and as far as pooling, I certainly would never pool efficacy from acute exacerbation of chronic bronchitis, and I would be somewhat reluctant to pool sinusitis efficacy with community acquired pneumococcal also.

DR. GOLDBERGER Yes, we weren't really thinking in terms, frankly, of acute exacerbation of chronic bronchitis.

ACTING CHAIRMAN RELLER: Dr. Archer, we are combining --

DR. ARCHER: Let me just say, since I was recused from yesterday afternoon's discussion, I abstain on this vote.

ACTING CHAIRMAN RELLER: Okay.

Dr. Parsonnet.

DR. PARSONNET: I agree with everything Dr. Murray has said. I don't think that there is

evidence, enough evidence, but I think from a physiologic perspective it's likely that it will work, so I would encourage the sponsor to collect more information.

I also think we can't really add the sinusitis in, since most sinusitis would clear up whatever you gave them. So, I think we really have to go with the pneumonia and have enough isolates of that particular category.

ACTING CHAIRMAN RELLER: I think the numbers are far too small to be comfortable with these strains, particularly, relative to the numbers shown yesterday, and even then I did not -- I favored having the data presented for what they were, and not a specific labeling after Streptococcus pneumoniae regarding the susceptibility or lack thereof to another agent, which, in fact, in what was presented, and especially in the very small numbers of bacteremic patients at least is efficacious, so that we don't have a label that says, you know, amoxicillin, including penicillin intermediate and penicillin resistant strains, for which there is certainly just as much data. And, consequently, I do not think this should be included.

DR. DANNER: I agree, I also vote no on

this issue. We are going to cover the issue of cases of bacteremia and severity as a separate issue?

ACTING CHAIRMAN RELLER: We can address that, but if we say there isn't sufficient information then, I mean, it may be -- you know, may come up again later.

But, I mean, we can, if you want to comment on that, please do so -- I mean, it's appropriate to do so now.

DR. DANNER: In addition to thinking there's not enough information on penicillin resistant isolates, I also think there's not enough information on patients with bacteremia, or looking at data showing us that in a category of severe pneumonia that the drug is effective.

ACTING CHAIRMAN RELLER: Dr. Soper.

DR. SOPER: No for the penicillin resistant issue.

ACTING CHAIRMAN RELLER: Dr. Christie.

DR. CHRISTIE-SAMUELS: No. I cannot recommend including PRSP, nor should we mention PISP. I think the numbers are too small for that.

In addition, I go back, and I still say that seven out of ten patients who got better with 70 percent, it was bacteremic Strep. pneumo., although

that was sensitive, but I still think we need much more information than that, because here you are dealing with a patient who is likely to be hospitalized and a patient that's likely to be more sick.

The other caveat would be, again, I think this drug, when it's approved, will be utilized in children, and I think we really need to collect a lot more data, and I outlined yesterday my concerns with Strep. pneumo., necrotizing pneumonias, and pleural empyemas among abscesses in children, I really think we need to study that more. We need to be very cautious if we utilize this drug in the pediatric population for pneumonias.

ACTING CHAIRMAN RELLER: Thank you.

Dr. Rodvold.

MR. RODVOLD: I agree with Dr. Murray and vote no on both indications. I think that some supporting information on the pharmacokinetics, both in models, it would have been helpful to add a little bit here to kind of reassure people. And, I think also that there's no concentrations, from what I understand, in patients.

And, yesterday Ortho McNeil's presentation had pharmacokinetic data in patients to kind of

reassure you, and you kind of wonder with this bacteremia number being different here, so I think in post marketing they may need to do a population analysis and get some numbers to see if the PK is the same, and that may be helpful also in the safety issues, and see what the concentrations in those patients are.

So, no, on the penicillin.

ACTING CHAIRMAN RELLER: Thanks.

Dr. O'Fallon.

DR. O'FALLON: No, on the penicillin, and bacteremia, no.

Can I say, I'd like to make one more, I'd like to match the screw up a little. One of the things that bothered me yesterday about the discussion was the fact that there were so few patients, and that's bad from a statistician's point of view, but the representativeness of those patients bothered me a lot.

I kept listening to the pediatricians, and I happened to be sitting between two of them, they were very concerned about the fact that these things are applying to children, without very much information at all, because there are -- the studies aren't being done in the kids. And so, when you have

them -- they also said that a very large percentage of the people that would be resistant, penicillin resistant, would be kids.

And, it just bothers me, I think that we've got to worry, not only about the total numbers of cases in considering the indication for penicillin resistance, but also the issue of who -- are those cases representative in any way, shape or form of the population that will actually be treated with it once the approval is given?

ACTING CHAIRMAN RELLER: Thank you for your comments.

What has come across very clearly is, and it's interesting because clearly there have been many discussions at these advisory committee meetings having to do with the questions about safety in children, but yet, the dilemma faced, you know, if someone has concerns about safety because of one issue then there aren't going to be the studies, but, yet, we hear over and over again that these compounds are used off label. And, that's something that, you know, will have to be somehow dealt with, because there are no indications for using these drugs for some of the very things that we keep hearing they are being used for, and that's why we need data, but they aren't

approved for using, and, therefore, I mean, it's a dilemma.

I don't want to get bogged down in this, but, Mark, whatever you want to say.

DR. GOLDBERGER: No, I'll just make a quick comment, as many of you know, Congress passed, not that long ago, a provision adding six months of exclusivity to either patent, orphan exclusivity or other types of exclusivity for companies in return, for instance, for performing pediatric studies.

You are all aware of the concerns that have existed in using the fluoroquinolones in children. Nonetheless, as more information has become available, we have been working with a number of the manufacturers about getting studies designed that would, (a) provide the kind of information everyone would like about both efficacy, short and longer term safety in children, and would hopefully help some of these manufacturers gain such exclusivity.

So, over the next months to a year or so, you will be seeing more information about a variety of studies that will become available with some of the fluoroquinolones to assess different diseases in the pediatric population.

ACTING CHAIRMAN RELLER: I think we're now

ready to move to question two.

We do have yes for all of the above indications, excluding the penicillin intermediate and resistant strains of Streptococcus pneumoniae in community acquired pneumonia. What labeling regarding QT interval produced by moxifloxacin is adequate? Is what has been suggested acceptable, or been proposed, and, if not, how would you change it?

Dr. Norden.

DR. NORDEN: It's not adequate, and I would suggest as a very simple and practical way of doing this, that we ask Dr. Ruskin, who stated, I thought, very nicely several points that should be included in the label, and I think this is really something where an experienced cardiologist could do far better than a committee of ID docs.

ACTING CHAIRMANRELLER: Could we possibly get the gist of it, realizing that this will be word smithed and refined by the agency as an alternative -- potential alternative labeling, that then we could make it more efficient to go around and see whether we like one or the other?

DR. GOLDBERGER: One just -- perhaps, as part of this, you had, you know, separated out the efficacy and safety vote, and the question came up as

to how you wanted to handle the issue of safety in terms of any voting, and I don't know whether you want to roll that over into discussion with question two as well. You know, we obviously defer to your discretion as to how to do that.

ACTING CHAIRMAN RELLER: I, perhaps, wasn't clear enough. I thought I already rolled it over into number two.

DR. CHRISTIE-SAMUELS: Excuse me, are we going to vote on safety or are we going to discuss it? I'm not clear.

ACTING CHAIRMAN RELLER: Okay. I think the most efficient way to do this is, are the data sufficient to have an unfettered, unadorned endorsement of safety for all of the above indications with this compound, yes or no? And, basically, what that implies to me is that, you know, there's no specific addressing of any changes or warnings with regard to QTc or any other specific safety issue.

Or, put another way - well, is this drug safe for all those indications or not?

Carl.

DR. NORDEN: No, I think it's safe, but I think it needs a warning label, and I think -- I mean, I would vote for its approval, if I were voting on

that specifically, but I would still like the label to be rewritten and I reiterate my original suggestion.

ACTING CHAIRMAN RELLER: Dr. Murray.

DR. MURRAY: I agree with what Carl said.

DR. ARCHER: Me, too.

DR. PARSONNET: Yeah, I agree with that as well.

ACTING CHAIRMAN RELLER: Aye.

DR. DANNER: I'm going to say no, and I'm going to say no because of the following reasons. I think when the drug is marketed, no matter what kind of warning you put in it, it's going to be used in substantially different ways than it's been used in the trials. And, I think that this is exactly the kind of place that you get into trouble with, when a drug is approved, it's carefully studied in a trial, people are carefully excluded who have prolonged QT intervals, are carefully excluded who are on drugs that can be additive with it in terms of the effect, and it's used for a very short interval of time, and so it's not clear -- I am absolutely convinced that the drug will be used differently once it's marketed frequently.

And, I think there are enough things that really haven't been answered. I don't know if the

drug effects potassium and magnesium excretion, and whether it somehow is additive with other drugs that produces increased loss of electrolytes through the kidneys, because that has not been looked at. It seems to possibly cause or increase the incidence of atria1 fibrillation, and we don't have real drug levels from real patients correlated with QT times.

So, I don't know, I'm just somewhat concerned.

The other issue with safety, obviously, is the risk benefit ratio, and I'm not sure I see what this drug adds to drugs that we already have that's so unique that we need this drug, that we absolutely need it, and we need it now for some indication. There are other drugs that you can use. They may have the same problem, but given that they haven't been studied in this way, I don't know that's the case.

ACTING CHAIRMAN RELLER: Thank you, Dr. Danner.

Dr. Soper.

DR. SOPER: I believe the drug is safe, and with the following comments. And, that is, I've had the benefit of a crash course in QT intervals, and my take home on this subject is that there's normal variability throughout the population, that this delta

of greater than 20 does not really reliably predict any adverse cardiac events, and that it's not quantifiable, so that the real risk with any of this data, literally, is unknown, that there are other drugs that have a similar, if not a more profound effect, that have already been approved and are in widespread use in this country, and that given the lack of information that we have, and the state of the art, where we are today, I think I would recommend we approve the drug as safe and effective, and then, as has already been alluded to, use Dr. Ruskin's recommendations with respect to safety issues until we get better data.

Thank you.

ACTING CHAIRMAN RELLER: Thanks.

Dr. Christie.

DR. CHRISTIE-SAMUELS: Well, I guess I'd have to say no, the data on safety are not convincing. It seems to me, based on the discussion, that the QT facts are clinically relevant, steady state concentrations needs to be studied further. In addition, the concern about people using the drug for longer than 12 days, I don't think we have enough information on that, and I believe that that may occur, even though that probably would not necessarily

be what we would recommend.

The other concerns about other drugs that might prolong the QT interval, the problems with hypokalemia, the problems with death after the drug was discontinued, and, again, the age-old problem, the use of this drug in children, I think we need to study the drug and the pharmacokinetics, and we also need to study the safety in the pediatric population. We need data on that, because although it was not studied, and although it won't be approved for children, I'm afraid it will be used in this population and I'm concerned about that.

ACTING CHAIRMAN RELLER: Keith.

DR. RODVOLD: I'd approve it for safety with the word smithing that it's going to be needed for the QT. The other thing, although we also need to be considering the label on that, prescribers realize that they probably shouldn't exceed this dose currently, because we just don't know what it is, and they've got to stay in the box of the dosing that they are recommending, and we may need to remind them that they can do whatever they want post marketing, but I think it's important to emphasize that to them as well.

ACTING CHAIRMAN RELLER: Dr. O'Fallon.

DR. O'FALLON: I was prepared to vote for safety with an appropriate change in the label, but the two that have talked about all the things that we don't know about, you know, the behavior of this drug have swayed me. I think I shall have to vote against, I don't believe we know enough yet about the safety because of the cardiac problems.

ACTING CHAIRMAN RELLER: Thank you.

Now, a greater exposition of question two, I think, Dr. Ruskin, that many of the members are looking to you for guidance for an alternative warning label to be considered contrasted to what has been proposed by the sponsor.

Yes.

DR. KWEDER: Dr. Reller, while it certainly isn't a part of an official vote, could we hear on the safety issue from the three consultants as well?

ACTING CHAIRMANRELLER: Oh, please, sure, with your request, yes.

Dr. Bartinelli.

DR. BATTINELLI: Yes, I would say that the information provided, the drug is safe, and certainly as safe as a number of other drugs approved, with the exception that it needs a more careful labeling with

respect to the QTc.

And, I agree with some comments that this drug, as well as all drugs that are on the market, will be used differently than they are actually labeled for. However, I believe that the only piece of information that the average clinician has to go on is, in fact, the warning label, which is very important and I think does bear more weight than some have given credit for.

ACTING CHAIRMAN RELLER: Dr. Ruskin.

DR. RUSKIN: I would vote yes on safety, with the caveat that labeling be very cautious, and that the sponsor buy in to participating in very careful post-marketing surveillance.

ACTING CHAIRMAN RELLER: Dr. Platt.

DR. PLATT: I was -- I thought Dr. Danner's summary captured a lot of my concerns, and I think that on balance we don't know enough now to conclude that it's safe.

I think the other thing that gives me pause is the fact that this is a drug that may be very widely used, so even if the estimates of one to two percent, which I think are very conservative, of meaningful QT prolongations are correct, that might be tens or hundreds of thousands of people who would

experience those. So, it seems to me that knowing more would be necessary for me to say yes, so I think if I had a vote I would probably say no for now.

ACTING CHAIRMAN RELLER: And finally, I'd like to make sure that there are no other comments that the voting members of the committee would like to make.

Dr. Parsonnet.

DR. PARSONNET: I just have one comment, which also echoes a little bit what Dr. Danner said, which is that although I think this drug is safe, I think we also have to consider the other drugs, other antibiotics that are out there, and whether the risk benefit ratio is as good as other comparators or similar drugs that are there. And, I think in balance this probably doesn't add a terrible -- it doesn't add very much to the antibiotic armamentarium that we currently have.

ACTING CHAIRMAN RELLER: A part of -- if necessary, we could vote on the proposed QT labeling, but it's my sense, from hearing all the discussion, and I certainly would agree with it, that I'm not keen at all about the proposed QT labeling as proposed by the sponsor, partly because there is wording about patients that we have little or no information

whatsoever, and other comments that have come out. And, consequently, for expediency I would like to hear the kinds of language that would go into, and if it would be in the form at your recommendation, and then we will have the voting members consider it.

Dr. Ruskin, would you put this in a warning label, and, if so, I mean of that degree of emphasis, and what would be the things that you would think important to include if you thought or if you would recommend a warning label?

DR. RUSKIN: Well, I was hoping not to get put in that position, but since you've asked the question directly I'll answer. I would include a warning label, and in saying that I guess I would also probably be inclined to urge that that be considered for other agents with similar effects, as we live through with the anti-arrhythmics, and that obviously the FDA will do a better job than I can with this, but to take a first pass at it, I guess it would say something to the effect that this drug is an Ikr blocker, or a weak Ikr blocker with a mild to moderate effect on the QT interval, that in the patient populations studied in the clinical trials no adverse effect on cardiovascular morbidity or total mortality was observed.

However, there are no data on safety in patients with preexisting QT prolongation or those currently taking other agents which prolong the QT interval and, therefore, the drug should be avoided in those subsets.

Furthermore, factors such as bradycardia or hypokalemia, which are known to exacerbate the QT prolonging effects of Ikr blockers, should be considered or approached with caution when using this drug in patients susceptible to those conditions.

Something along those lines.

ACTING CHAIRMAN RELLER: We'll go from my left around.

Dr. Kweder.

DR. KWEDER: As a follow on to that and, perhaps, something else the committee could consider in thinking about language, one of the tools that we have employed with increasing frequency is the requirement for a patient package insert with a drug, particularly, for those that are going to be administered in an out-patient setting. I wonder how Dr. Ruskin would comment on the appropriateness of that in the case of this drug.

DR. RUSKIN: I think it's a great idea.

ACTING CHAIRMAN RELLER: So that we have

something to work with and people can disagree and we can come back and make substantive revisions, do you want to include that as part of the warning package?

DR. RUSKIN: Yes.

ACTING CHAIRMAN RELLER: Now, we'll come to the committee members, and is what is described, both the general wording, as well as the patient information component, does that satisfy your concerns about safety of this drug for the moment?

DR. NORDEN: Yes.

ACTING CHAIRMAN RELLER: Dr. Murray.

DR. MURRAY: Yes.

DR. ARCHER: Yes.

DR. PARSONNET: Yes. I have, actually, an FDA question, which is, when we put this warning label on this particular drug, what happens to the drugs that it interacts with? Do you then add it to the list of drugs on those warning labels, so that when somebody is on this medication and three days later their doctor says, well, you now have atria1 fibrillation, we are going to put you on an anti-arrhythmic, is it going to be in that anti-arrhythmic's description label that says being on -- previously being placed on this antibiotic is a contraindication?

DR. KWEDER: That's a challenge, and we try to deal with that as best we can. I mean, it gets to the point where some of these drugs have exhaustive lists of potential drug interactions, and as we go along we do try to update them as best we can.

It certainly does offer a particular challenge when you are dealing with drugs that are for totally different indications, like an anti-arrhythmic and an antibiotic, but we will attempt to do that.

DR. PARSONNET: Because it is quite conceivable that somebody will be on this drug first and have something else added on.

DR. KWEDER: Absolutely.

DR. PARSONNET: And then, if it's not in the label for that particular medication it may be missed.

DR. KWEDER: Right.

ACTING CHAIRMAN RELLER: Thank you both.

Bob.

DR. DANNER: I'm a little confused by what we are voting on. I mean, my answer is still no from before. I agree that if the drug is approved that it has to have a warning label similar to what's been described. I also wonder whether it shouldn't include something about the possibility that it may induce

atria1 fibrillation in patients, particularly, patients at high risk for that arrhythmia. And, you know, whether it should contain information about the drug effect on QT may be aggravated by hypokalemia and, therefore, potassium levels, particularly, on patients who are on drugs that cause hypokalemia should be monitored, or at least baseline checked.

I mean, I think there may be other things that need to go into the warning label to caution people.

I would also suggest that it say something about the fact that in the trials prolonged use of the drug, in terms of its cardiovascular safety, were not assessed, you know, by giving it longer than stated.

You know, in terms of the other drugs that have been approved, I guess one of the problems that the pharmaceutical company has here is that, you know, they were, perhaps, the first to come along, take a drug with this issue and evaluate it so thoroughly, so it's probably, you know, raised as many questions as it has answered.

In the other drugs that have gotten approval, where a number of thousands of people have been studied, I guess I'm not sure in all of those that people on Class 1A and Class 3 antiarrhythmics

were excluded. So, in fact, if they studied those types of patients and didn't have an increase in problems, that would suggest that, perhaps, those drugs may, in fact, be relatively safer than we know this drug is, just because it hasn't been looked at in those populations. I don't know the answer to that.

ACTING CHAIRMAN RELLER: Dr. Danner, thank you for your comments, all of which are recorded here for consideration, and we'll come back to some of these issues on the last question, I think, as well.

Dr. Soper.

DR. SOPER: Yes, with the warning label as discussed.

ACTING CHAIRMAN RELLER: Dr. Christie.

DR. CHRISTIE-SAMUELS: Yes, with the warning label as discussed, and I guess we would also say that it has not been approved for use in children.

ACTING CHAIRMAN RELLER: Thank you.

Keith.

DR. RODVOLD: Yes. As I mentioned before, and in view of what Bob just said, I'd put a dose duration, reemphasize that this data is around only this information at this time, and we don't know what it is outside of that, so just a friendly reminder of this dose and duration that's been studied.

ACTING CHAIRMAN RELLER: Dr. O'Fallon.

DR. O'FALLON: Yes, with the various -- I would vote for all the amendments that have been suggested.

ACTING CHAIRMAN RELLER: And, I also, for the record.

Question three, if moxilactamis approved, what -- I thought we needed some comic relief at this time of the day -- how's that for a recovery -- okay, now question three, if moxilactam -- could you read the question, Julie? No. If moxifloxacin is approved, do you have any recommendations regarding Phase IV studies for data collection that the applicant should be requested to perform?

Carl, what studies data to you want to see?

DR. NORDEN: Well, I think the one I would most like to see is the one that Keith mentioned, and I think all of us were asking about, and that is PK data, concentrations in patients, not just in healthy volunteers, because I'd really like to know whether this is the same, or as I suspect it will be different for sick patients, as opposed to healthy volunteers. I think that would be very useful.

ACTING CHAIRMAN RELLER: Barbara.

DR. MURRAY: Studies such as we heard yesterday focusing on pneumococcal pneumonia, penicillin resistant susceptible strains, if the desire is to get that as an adjunct or a supplement to the labeling.

DR. ARCHER: I think prospective studies looking at -- continue looking at QT prolongation with this and similar compounds, but this one, since so much data has already been collected, to look at data in patients where applicable, and interactions with other drugs that might be pro-arrhythmics.

DR. PARSONNET: I agree with all those studies. I would be interested in knowing whether people actually follow the warning labels and whether they actually adhere to what is recommended, and whether there's a way to access that data. And, I'm also just very curious about this AF phenomenon, and although I wouldn't -- I don't think it's necessary to include that in the warning label, I would be interested in seeing whether there's any animal information that could be obtained about that, and I would certainly want that to be included as one of the things they followed up to see whether it occurred with greater frequency in follow-up studies.

ACTING CHAIRMAN RELLER: Dr. Danner.

DR. DANNER: Well, I agree with all of that, in terms of the further studies and monitoring, and I would like to see more data in bacteremia in patients with very severe illness due to pneumonia, such as patients requiring intensive care units, and I'd like to see information on whether the drug has an effect on potassium or magnesium excretion, whether those -- and whether those effects are added are synergistic with other drugs that have that effect.

ACTING CHAIRMAN RELLER: Dr. Soper.

DR. SOPER: I have nothing to add.

ACTING CHAIRMAN RELLER: Dr. Christie?

DR. CHRISTIE-SAMUELS: I'd be interested to learn more about the QT factor at relevant steady state concentrations, as discussed previously. I'd love to hear more about how the drug performs in patients with bacteremic pneumonia, not only penicillin susceptible strains, but penicillin resistant strains as well. I'd also like to learn more about the drug performance in patients who have community acquired pneumonia with pneumococcal isolates. I'd love to learn more about the drug in children, the pharmacokinetics, efficacy studies, especially in patients who have pneumonia, again, stressing what I said yesterday.

ACTING CHAIRMAN RELLER:

DR. RODVOLD: I'll go ahead, Barth, and I agree with what has been said. In regards, I'd urge sponsors to pursue the penicillin resistant indication if they wish, but I'd also encourage them to use studies that would be a little bit more helpful, maybe more domestic studies, controlled studies, blinded randomized, so that we are not kind of sitting on the edge of knowing what's going on, and so that when they present the data that it comes across more convincing, and the numbers would be up in -- and I think they can do that all post marketing, in addition to the safety hopefully, and they might be able to get by with a couple of good controlled studies and be back on the table within a year or two, or whatever it's going to take, and try to combine as much of that as possible for us to get it all clinically relevant.

ACTING CHAIRMAN RELLER: Judith?

DR. O'FALLON: I agree.

ACTING CHAIRMAN RELLER: I think it was mentioned earlier that it would be difficult and would need some courage in requiring close observation, but I think Dr. Ruskin pointed out earlier that if – Dr. Temple -- that if studies were undertaken in what people had the greatest concerns about of

interactions, and a controlled situation to delineate that, to see whether these are competing for the same receptor mechanism or, in fact, are additive and get up to a magnitude that poses a risk would be helpful in the long run.

Question four.

DR. GOLDBERGER: Dr. Reller, can I just ask Dr. Ruskin whether there are any other specific studies he might want to suggest that might better elucidate some of the issues as far as the risk of the QT prolongation, either clinical or preclinical.

DR. RUSKIN: No, I think they've been pretty well covered. I guess the one drug that would interest me, just because of its extraordinarily widespread use, would be an interaction study with cisapride, but other than that I think all of them have been covered.

ACTING CHAIRMAN RELLER: Dr.s Battinelli and Platt, do you have anything you want to add here?

DR. PLATT: One additional thing that I think would be worth knowing is the impact of moxifloxacin therapy on acquisition of resistance by pneumococci, and that might be learned by doing nasal swab surveillance for pneumococci after therapy, even though it's not the organism being treated,

understanding whether this change in MIC would be fairly helpful.

DR. BATTINELLI: I would just add that in addition to cisapride, some of the other drugs that a number of patients are on, that the usual family practitioner, internist or other person prescribing this agent, doesn't know a lot about all the anti-psychotics, and frequently patients are on those medications and don't report being on those medications, so I would also study those as well.

ACTING CHAIRMAN RELLER: These comments reminded me of something that I also would be interested in, and I realize it may be difficult to obtain, and that is, there were very few clinical failures in the patients with pneumococcal pneumonia, but when there were failures either we don't have or the patients weren't cultured, and I think it would be those patients that we'd be particularly interested in finding out whether the organism that persisted, if there be any, is markedly different in its susceptibility to this or any of the newer compounds.

Question four, do we have any recommendations regarding the parameters, both qualitative and quantitative, that might be most useful in assessing the significance of QT

prolongation caused by anti-infective products, and I'd like here to actually begin with our consultants, and just for consistency we can go to Dr. Battinelli and then to Dr. Ruskin and around for the voting members.

DR. BATTINELLI: I think some of these things have already been mentioned, that most interested in making sure that there's good data on concomitant drug use. I think the sponsor has established the rigorous protocolbywhichprospective or potential patients who are normals, et cetera, are studied, but not enough data on people taking the additional medications.

DR. RUSKIN: I think we've hammered this pretty hard today, and I guess I would start by saying that what Bayer has done might serve as a model for working up a drug that affects the QT interval. This is really a lovely evaluation all the way from the preclinical through the clinical.

The important issue is, if you see a signal of an effect on a QT, to go back and do an Ikr screen, and then to look at single cells, usually guinea pig myocytes and hysperkingy tissue, isolated profused rabbit hearts, intact dog hearts, for a whole host of parameters, so that you look at a number of

different models, one over a very wide range of drug concentrations and heart rates, be very careful to screen for metabolites and make sure that the clinical data are collected in a very careful and rigorous way, as detailed by Dr. Morganroth.

So, I think it really is a package, and I would have to say that this is certainly among the best of them that I've seen. So, if FDA is looking for guidance, this is probably a very good place to start as a model.

DR. GOLDBERGER: You know, it wouldn't be uncommon to have potentially some of the preclinical data done first, or very early on, certainly before the Phase III trials. Does the preclinical data, if a negative result occurs in that, is that sufficient even if you were worried because of the class of drugs to not have to do a lot in the Phase III trials, or are you basically saying that both preclinical and clinical data should always be obtained if there's any type of signal or suspicion?

DR. RUSKIN: I think the preclinical data is critical, and most of the experience would suggest that if the drug doesn't affect Ikr that you are probably pretty safe. So, that's really the place to start.

If the drug has Ikr blocking properties, then I think it opens Pandora's Box in terms of having to run the gamut. I don't know how --

DR. GOLDBERGER: So, you would think that's a reasonable screening test?

DR. RUSKIN: Well, I think it's a very good place to start. The likelihood of having a significant clinical problem if you don't effect human Ikr is pretty minuscule.

ACTING CHAIRMAN RELLER: Dr. Temple.

DR. TEMPLE: We are actually actively looking at that. There's a lot of data on a lot of drugs, and there may be a difference, we don't know this for sure yet, it depends on what the concentration that inhibits the Ikr is. Our dream, our hope, is that you can find a cutoff point above which you are not worried, because the concentration needed is so large, and there's at least some sense that it is breaking down that way, where the receptor is very sensitive, you have the class of drugs that cause trouble where it's hardly sensitive at all, and you need a very large concentration to inhibit, those look more or less clean, and in the middle you have to do a lot of work.

DR. GOLDBERGER: Dr. Reller, could we also

hear as part of this from Dr. Morganroth?

ACTING CHAIRMAN RELLER: Sure.

DR. GOLDBERGER: Okay.

DR. MORGANROTH: My only addition to it was just said, is that I'd be very cautious to assume that Ikr data is simple, you know, black and white, like getting a serum potassium is. As heard, it's concentration dependent, model dependent, in whose hands it is. So, if you are about to start a new drug and you set up the model in your lab in your company and you find it to be negative, you know, that would make me very comfortable.

But, as Jeremy said, if you do it in a bunch of models and in a bunch of concentrations, et cetera, and you really work it up well and it's negative, I still think that like doing liver function tests is an analogy, if you screen toxicologically and you don't think a drug affects the liver, how many of you would be comfortable going into a clinical drug development program and not obtaining in man liver function tests? I mean, you wouldn't even raise that question, of course you would do that.

In the past, we've not done electrocardiograms on every single drug ever taken into man in the non-cardiac field, because they don't

affect the heart, they are non-cardiac. But, we've now learned that so many drugs appear to affect the QT interval that were unexpected that I simplistically would suggest that the EKG, just like grabbing, you know, 'the CBC in a chemistry panel, it's not irrational to include EKGs with every -- as a simple point of safety. When do you do that? Well, you don't do it before the drug is given, you know, and then after the drug is given, when would you do your CBC, liver function tests, you would do it during at least acute dosing, and then you would also want chronic exposure. And, I think EKGs belong before, during acute exposure, and afterwards, and I think they should be centralized like most blood studies, and I think they have to be analyzed with the attempt to try to find three, six, ten milliseconds, rather than by eyeball where there's a lot of noise.

So, my answer to number four is, you do need preclinical, you do need clinical. The preclinical only tells you what your risks are, and you may, even with a positive Ikr because of therapeutic benefit, go into man, but on the other hand if you are not so sure of the benefit risk you may pick another drug in that sequence or not move into man because of the risks involved, and that when

you do it, and how you do it, should be very similar to any other safety test that you do and making this very simple.

ACTING CHAIRMAN RELLER: Dr. O'Fallon.

DR. O'FALLON: Now, is the question, do you have any recommendations, et cetera, with these recommendations, is that the --

ACTING CHAIRMAN RELLER: Do you have anything to add in addition to what's already been said?

DR. O'FALLON: No, I don't. Thank you.

ACTING CHAIRMAN RELLER: And, Dr. Platt, I think I skipped over you when we diverted to Dr. Morganroth, whose comments we much appreciate.

DR. PLATT: Well, I'll comment from an epidemiologist's perspective, to say that often what we -- another thing that is important to focus on is the absolute level of risk, not the relative risk, so that I think in the risk assessment for all drugs, and this class of QT prolonging drugs as well, it's important to contemplate in the target population what's the number of people who are likely -- who might plausibly be adversely affected, as opposed to the percentage.

And, the other comment I'll make is that,

among drug safety problems, this is, I think, among the most difficult to tease out using traditional post-marketing surveillance methods, that the system that Dr. Brinker described, and some of the databases that draw on large populations that are very useful for understanding other kinds of adverse drug reactions, are not very good for these kinds of reactions. And so, when there's a judgment to be made, there's more emphasis that will have to be put on the formal clinical evaluations.

ACTING CHAIRMAN RELLER: Thanks.

DR. RODVOLD: I have nothing to add.

DR. CHRISTIE-SAMUELS: I have nothing further to add.

DR. SOPER: Nothing to add except to amplify Dr. Platt's comments. I mean, I think that absolute risk and predictive values of some of these parameters that you are measuring with real patient outcome is an important target, and all of the money and work that goes into looking at measuring something, if it's not predictive of poor outcome I'm not sure it's worthwhile.

DR. DANNER: Nothing to add.

ACTING CHAIRMAN RELLER: Julie, Barbara. Before they had to leave, Dr.s Archer and

Norden affirmed, and I would like any comments from the committee, and this is, Mark, for you and your colleagues at FDA, and we can assume this would happen, but I'd like for the voting members of the committee to give a sense of their feeling of need for it, and that is, as more has been learned and discussed about this specific agent, we together, Rhonda helped to just pull forth the package insert on specifically sparfloxacin, grepafloxacin and clarithromycin, and all of them have language different from what has been proposed, but related to the QTc issue.

And, I would think it would be wise for fairness, for consistency, for understanding, realizing that some of these compounds, while these compounds were approved before we had the kind of database that is available here, to whatever, within the regulatory capabilities are possible, to go back and look at some of the questions that have been raised if the data are extant, including such things as what Dr. Ruskin pointed out, were patients with certain conditions excluded from the outset, so that there are no data and that the risks and the comments about the QTc intervals may be made on a patient population that is different from the ones that have

been discussed so thoroughly here today.

But, the essence of all of this is of trying to get consistency, equity, fairness and detecting real differences if there be them, which there have been for other values, between the compounds within a class and across classes that relate to a particular kind of safety concern.

Dr. Murray, would you like to see that happen?

DR. MURRAY: Yes.

ACTING CHAIRMAN RELLER: Dr. Parsonnet.

DR. PARSONNET: Sure.

DR. DANNER: Yes.

DR. SOPER: Yes.

DR. CHRISTIE-SAMUELS: Yes.

DR. RODVOLD: Of course.

ACTING CHAIRMAN RELLER: Okay.

DR. O'FALLON: Yes.

ACTING CHAIRMAN RELLER: Dr. Goldberger, we have tried to address the questions you posed, and a few additional ones, and have broken up, even added a few compounds that you never wanted us to consider, dropped quickly, or not so quickly, do you have any, or Dr. Kweder, any concluding -- any comments that you want to make? We are about to wrap this up.

DR. GOLDBERGER: Yes, my only comment would be to thank the committee and the consultants for their comments and opinions, which I actually, I think have been quite useful. I'd particularly like to thank both Dr. Ruskin and actually Dr. Morganroth, even though he came here with Bayer, for their comments, which I think have helped a substantial amount in terms of our, you know, thinking about a possible framework for evaluating current and future compounds.

ACTING CHAIRMAN RELLER: I'd like to thank everyone's efforts to speak what they think and to do it succinctly, and this Anti-Infective Advisory Committee meeting is concluded.

(Whereupon, the meeting was concluded at 3:32 p.m.)

CERTIFICATE

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

Before: ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE

Date: OCTOBER 21, 1999

Place: SILVER SPRING, MARYLAND

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

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