

using tympanocentesis at baseline to establish microbiologic etiology, and this is the first point where we were actually listing 25 patients with Strep. pneumoniae, 25 patients with Hemophilus influenzae and 15 patients with Moraxella catarrhalis.

Now, I would, also, point out that in November 1992, in the CID there was a collaboration between FDA and IDSA, also, looking at studies looking at anti-infective drugs and that included, also, a recommendation about studies for acute otitis media that made similar points to this.

So, now, we move forward in time to 1998, and to the draft guidance for industry document that we have.

Now, in that two studies are again recommended, and this should look familiar, very similar to what was in the points to consider document.

Here we just say another trial as opposed to specifying that it can be an open study and otherwise the trials are the same, so, the first, being a clinical only study as we have defined it in your briefing packets from the FDA and the other a single tap study.

Now, for the first trial, the clinical only study the caveats that are made are ordinarily should not enroll children less than 6 months of age and Dr. Wald had brought

up this question earlier today, and from what I could tell from looking at those documents there were concerns about the accuracy of the diagnosis of acute otitis media in those children less than 6 months of age and that was part of the reason that those patients were excluded.

There was another caveat in our guidance document related to rigid case definitions and the goal there being to try to create case definitions that would identify within the clinical only studies those patients who are most likely to have a bacterial infection.

Now, in this study it says that baseline tympanocentesis need not be performed, but we do say that tympanocentesis of patients that are judged to be therapeutic failures is strongly encouraged to document potential specific bacterial pathogens that are not adequately treated within the trial.

Unfortunately, what we end up with especially from the clinical only studies is that we rarely, if ever see information on tympanocentesis done in patients who are therapeutic failures.

Now, for the second trial, the micro study, again, post-therapy tympanocentesis is encouraged in patients that are judged to be therapeutic failures. To identify that we want to have at least two investigators in

geographically diverse regions for the pivotal studies for microbiology, and there is a quote that relates to acceptable clinical and microbiologic effectiveness of all three organisms in which case if we don't have what we think are acceptable effectiveness against all three microorganisms then for those organisms where effectiveness is in question, we specifically don't list that as, that we can specifically exclude that from the indication where we typically list it as otitis media due to and list specific pathogens, and we could, also, put in a statement that says that it is restricted use and not as first-line therapy.

One of the other caveats in the draft AOM guidance is related to resistance in *Strep. pneumo*, and we make a statement saying that 25 patients may be insufficient when you are looking at a question of a drug that might be effective due to a resistance mechanism, especially if the resistance mechanism, for instance, penicillin resistance would affect your particular drug like a beta-lactam antibiotic.

Now, I am not planning in going through in detail all the inclusion and exclusion criteria and the guidance document as it currently stands is within the briefing packet that you were sent from the FDA.

I did want to make some points related to the

study visits and the way that the draft AOM guidance currently reads there is an entry visit. On therapy at 3 to 5 days there is a strongly recommended visit in order to assess the clinical status of patients at that point. The end of treatment in the guidance is currently optional and the test of cure stands now at sometime between 2 to 4 weeks after entry is when the test of cure visit should be held.

So, it is not out to 30 to 42 days and sort of later follow-up that had been seen earlier. There is a late post-treatment follow-up that is offered as a sort of an optional visit and that is related to the presence of middle ear effusions that you can follow patients out to around day 30 to see whether middle ear effusions persist or not.

For the most part we don't think that beyond that point whether a middle ear effusion is present or not is really related to the effectiveness of an anti-infective drug given 30 days earlier.

Now, in addition to these guidance documents we have had four different advisory committee meetings out of the past 11 that have in some way addressed acute otitis media, and I am going to make points related to each one.

In spring 1997, we had an initial presentation of

our guidance document and this was within the context of actually presenting several different guidance documents on several different indications so that the discussion about acute otitis media was about an hour or so worth of 2 days of meetings, 2 or 3 days, but some of the issues that came up during the discussion after the initial presentation of this guidance, one was related to baseline clinical findings and again making the point about concerns about how do we get a case definition that will adequately define those patients who are likely to have a bacterial infection and truly need an antibiotic for treatment especially for the clinical only studies.

There were some comments at that meeting about the timing of the test of cure visit and at that point these were just a few comments that were related, some questioning what is the value of taking a look at the end-of-therapy visit when the 2-to-4-week visit is probably acceptable, some comments that were pushing towards looking at the earlier time point, the day 3 to 5 visit as an important point to look at clinical efficacy of the drugs and that is why the, that is in part why the guidance reads the way that it does, having a test of cure visit at 2 to 4 weeks and making a strong recommendation for an on-therapy visit at day 3 to 5.

One of the other issues that came up was addressing the number of Strep. pneumoniae isolates that were needed in light of the increasing resistance, and that is where the comment that I had made before about 25 patients may be insufficient with Strep. pneumo, but that is not really something that we likely to get into a great deal today.

Then the fourth issue that was discussed was related to follow-up of middle ear effusions out to 30 days, and again I made those comments earlier with relation to the post-therapy late follow-up visit.

Now, in fall 1997, we had a meeting on ceftriaxone for acute otitis media and for the most part the discussion focused on the product itself as you would expect.

There were at that time also comments that were made related to the resistant Strep. pneumoniae and concerns about how to adequately address those patients within the designs of these trials, and there were, also, other comments that were related to study design. For the most part they addressed the issue of the use of pre-therapy antibiotics, studies which excluded patients who had antibiotics more than 30 days or less than 30 days prior to starting the study versus just less than 7 days.

In 1998, we revisited the guidance and the FDA presentation was of changes that were based on the spring 1997 advisory committee where those issues were discussed and leading to what I had presented as what our current draft guidance for AOM is.

At that same meeting there was a lot of discussion that surrounded the letter from the CDC to the FDA and this is a quote from the recommendations of the CDC that since clinical only studies would need to be prohibitively large to detect a difference if one truly existed between two drugs that they were recommending smaller bacteriologically driven studies that would be more effective in showing the effectiveness of a drug.

So, at that point there was a lot of discussion about the different trial designs and alternatives and some of the members of the Committee that were there during that point are here today and hopefully can speak to some of those points.

There was, also, a lot of response from the industry during that advisory committee meeting about the concern of how to do even single tap studies, about the difficulties of enrolling patients in those trials and again, what ended up being left after this meeting was over was the current copy of the draft guidance that you have in

your briefing packet.

In January of this year we had a meeting that was on Augmentin ES-600 and I am hoping even more of the Committee was here at that time and will remember that. Again, the discussion focused on the particular product. We, also at that time asked questions related to the timing for the test of cure visit and got some input as to actually looking more towards the end of therapy visit as opposed to the later 2 to 4 week test of cure and there were, also, comments made at that time related to the assessment of bacteriology and clinical failures and how that could potentially be important which leads us to today and again, today's discussion focused on the product itself and it seemed natural from the issues that were being discussed that there are issues related to clinical trial designs that we would like to have some input from the Committee on.

Now, I wanted to make at this point it clear that anything that we do in terms of trying to address the guidance in the future and from comments earlier today as well as from comments at the augmentin ES meeting it seems apparent that we are likely to need to change the guidance document, but any kind of changes would be something that we would probably announce in terms of the Federal Register

and open it for comments from the public, looking at different fora to get experts in the field together and probably again take it to another advisory committee where our purpose is to actually discuss the guidance document itself rather than to discuss a specific product.

But given that we do have some issues that we would like you to discuss further and flesh out for us as sort of a lessons learned from today's discussion and these questions are intended to be in a way provocative in order to try to engender some discussion, the first one, should clinical only trials continue or should all enrolled patients have a tympanocentesis at baseline. The second question is should the non-comparative microbiology studies continue; so, should we be actually looking for only comparative data.

A third is should guidance incorporate stratification by age less than 2 years and if so, what proportion of patients should be under the age of 2 years, and what we would like you to consider in your discussion is to comment on the merits of studies with clinical information only, studies with tympanocentesis, the ideal timing of clinical assessments, the end-of-therapy versus a later follow-up and alternative study design, so, comparative trials with microbiology, double-tap studies,

placebo-controlled studies with early escape if you can define an appropriate population and we are hoping that what these, what we have outlined here will be issues that the Committee will discuss more thoroughly, and before I stop talking I would just like to acknowledge the hard work of all the review team as well as the contributions of the entire Anti-Infectives Division to putting together the information for this meeting today.

Thank you.

DR. RELER: John, thanks very much. We look forward to the discussion. I think it will be rigorous and people will make pointed recommendations for your consideration.

Who wants to open it up? We will take question No. 1. Should clinical trials, clinical only trials continue?

Dr. Dagan?

DR. DAGAN: I think that you like to have efficacy data, but you need, also, to have safety data, and if you do very, very thorough studies with microbiology, let us say even with tympanocentesis and you get a relatively small number of kids with very good efficacy data, you still are not going to have enough safety data.

So, I think that for that purpose you need studies with a lot of kids, whatever is your criteria for getting satisfactory safety data. So, I think that this discussion should be separated for efficacy and for safety and since for efficacy you may find yourself eventually hopefully for me at least, I hope that you will be doing less kids but more thoughtfully studied then one would like to divide this into if one needs more kids for safety what are we going to do, just give the drug and see the safety or are we going to design a study that looks for clinical outcome and within that to build on the safety, and in my opinion therefore the first bullet is yes, we should do clinical only trials but as a secondary importance for efficacy but probably important for safety and then, of course, it is answered the same way, should we, the lack of comparative microbiology studies, I guess this is all related because I think this is the wrong, I am sorry, I think this is the wrong sentence because if I understand what you want it is when drug only with no comparison to another drug but the other comparative microbiological studies if you do the ears or if you do azithro or whatever and then with azithro we did see cases; it was not done in double tympanocentesis but you have different cutoffs of MICs and actually these are double-blind studies because

when you look at the second tympanocentesis or when we look at whatever you don't know the outcome. You are just going to more to tap. You do the evaluation and how are you going to see what happens and then break it by MICs and you see if you have very sensitive susceptibility, make it susceptible and resistant and you look at the clinical outcome. This is extremely nicely constructed double-blind comparative study but instead of comparing azithro to augmentin you contrast susceptibles to intermediate or resistant and then you can come with what type of cutoff to approve to children.

So, I think this is extremely important and they are comparative, but they don't compare one drug to another, that although they give you actually the most important information, this is up to what level of resistance you should still approve that drug and if you ask it as well of your requirements then the sample size should be calculated and then people are going to come with enough data, not just 1 of 6, 3 of 20 and 1 of 4 or whatever. They should calculate the sample size to answer that question which is extremely important, I believe.

DR. RELLER: Dr.Marchant?

DR. MARCHANT: Notably absent from the questions posed is the question of what differences are you looking

for and what sample size is needed to calculate. If the guidance doesn't address that issue then we will continue to look at a lot of small studies, look at a lot of data which never would have shown any difference. An example would be the questions raised whether you should look at 25 pneumococci or more because there is resistance.

Underneath that question is really still the question of sample size. What you question, what is an important difference in terms of pneumococcal resistance, how many resistant serotypes do you need to look at versus how many sensitive; what kind of outcome and all that underneath all that question is the size of the expected difference, the important difference and the sample size questions from that and if this guidance continues to ignore that, then these meetings will continue to on the basis of very small studies that wouldn't have passed the tap water standard to approve drugs or regimens that are not effective. So, that is absent from the mix here.

So, even addressing question 1 you need to figure that into question 1.

DR. RELLER: What do you think it should be?

DR. MARCHANT: Well, I think, so, this is clinical; so, actually those are the same questions here. Well, I think that if you do a tympanocentesis at baseline

you have a better chance given any given sample size of showing a difference than you do if you do not do tympanocentesis at baseline, but the fundamental problem is you need to if you are going to do a single tympanocentesis study and look at clinical differences you need an outcome that you are going to be able to show a difference with or you are not doing a scientific study. You are going to stay under the tap water standard.

What is that difference? When you look at the clinical data from placebo-controlled trials the maximum difference you can find between a placebo and a drug is about 15 percent for some end of therapy outcomes, and that is with enriched populations that are highly symptomatic and not just taking all comers.

So, you have to then link not only the sample size questions to the outcome but also to the population you choose to study the outcome in and all those things can be calculated based on samples in the literature, but the question has to be refined more.

DR. RELLER: Dr. Dagan, Dr. Jacobs, yourself and others on the Committee have, there have been some very thoughtful and specific comments made on clinical trial design.

If you were the FDA what would you want done to

consider first the efficacy and then as Dr. Dagan pointed out the safety? What numbers would you want? How would you do it?

Let us say you could just unilaterally make the decision. How would you want the data presented?

DR. MARCHANT: I am going to broaden your question, but I am going to get to all of it. The first issue I would do is as follows: Because the analysis that I presented that Dr. Jacobs presented and Dr. Dagan and so forth, I would do a double tympanocentesis study and I would look for a sample size which will detect the difference between a drug that is 90 percent efficacious bacteriologically and one that is 70 percent efficacious and that requires under 300 total recruited patients to do it.

Now, do I like double tympanocentesis studies? No, I don't entirely. I mean it is a painful procedure and as I mentioned in my recommendations we need to look at how to deal with the painful procedure part of it. My colleagues whom I respect in the academic field who, also, don't like tympanocentesis believe that we could show differences with clinical outcomes if we really drilled down and focused on better clinical outcomes, and that would include specifically saying, "How was the child on

day 1 and day 2 and day 3 and so forth?" and then summing a cumulative response over time, that kind of approach to get at it. Studies should go on to develop a better clinical outcome because maybe there is something we can do by looking at clinical outcomes. I don't exclude that, but that is, also what we should do. In the meantime we should be doing double tympanocentesis studies if we want to show, find out whether drugs work or not, but I am not saying that that should be forever and ever the approach. There could be new science and better outcomes looked at.

For safety how big should that be? That is, also, the question you are asking. Well, you should take an event like well, okay if I don't like 2 days of vomiting, that that is a side effect that is very troublesome clinically and I want to detect whether my drug makes kids vomit for 2 days and I care that, you know we have to make a judgment here, and I care that if a drug had 10 kids out of 100 let us say that had that outcome.

Then you can calculate the sample size that it is going to take to show a 10 percent increase over the baseline noise that you see in clinical studies with antibiotics, and there are ways to calculate that sample size. Statisticians know how to do that.

So you define, and that is rather asking the

total sample size for safety as Dr. Dagan mentioned and on the vaccine side, for example, they are getting interesting events that would occur 1 in 1000 or 1 in 10,000 and then you start driving up your numbers but it depends on how severe they are, but you should be able to create some professional guidance about how big a safety problem you what to look for. Again, it is a statistical question on the safety side just like it is on the efficacy side.

Have I addressed your question?

DR. RELLER: You have got us started because then we can come around the Committee as to whether or not this is in the ballpark, should be more or less, but, John, you had a comment?

DR. ALEXANDER: In order to try to focus the discussion a little bit more on the issue of efficacy one point that I would make is that typically when we are dealing with safety where we are talking about drug exposure what we are looking at is not only studies of acute otitis media, but we have, also, got studies of patients receiving the drug for pharyngitis, studies of patients receiving the drug for multiple other indications that could include young children and so for the purposes of the discussion I think that what we would like to try and sort of focus more on is the issue about really

demonstrating effectiveness in acute otitis media.

DR. RELLER: One approach might be that if someone comes with an outcome for which there already is an appreciable experience with other indications that could be included in the presentation but if we didn't have that you may need larger numbers at the outset with a new drug, a first indication but again those numbers could be forthcoming from within the agency and the consultants thereto on the statistical aspects.

So, let us concentrate on the efficacy.

Dr. Cross?

DR. CROSS: I think what we would like to do to handle the efficacy issue is to actually enroll informative patients as opposed to less informative patients. I think that in the last 10 years since many of the guidelines have been written for this and other processes we have learned a lot through clinical research who are the high-risk patients who are the more severe patients. This is certainly true in our last discussion on sepsis. It is certainly true in issues of febrile neutropenia and I think in each of those areas we see in these studies patients who might not be as important in the case of febrile neutropenia folks who have very short durations of neutropenia as opposed to long durations. In the case of

sepsis we had the issue last time of patients who were more informative at the more severe end.

I think that Dr. Dagan had a very nice presentation of what we have learned over the last 10 years in terms of which patients are more likely to have difficulty with therapy than others. I think if there is something which we might be able to add in terms of having some mix of severe patients who might be more informative based on a previous experience I think that would be very helpful in evaluating patients.

DR. RELLER: One of the things I would like to comment on in the emphasis on the tympanocentesis and I know that there are different views, that they shouldn't be done and they are very important, and Dr. Marchant has pointed out that smaller numbers, better studied would yield more information and one of the things that struck me over the time span that we have had these discussions on otitis media is the field has shifted, that the decrease in *Hemophilus influenzae* with immunization and the conjugate vaccine for pneumococci, Dr. Glode pointed out some forthcoming information that may continue on the interaction of antimicrobials and immunization practices and to me the beauty of tympanocentesis and the microbiology and of course it applies to resistance issues

as well is then you have a study design in place that can capture the ground that is constantly shifting underneath you whereas these differences clearly get buried with the emphasis on clinical outcomes, particularly clinical outcomes at a time when the reinfection rates are very impressive to me when you look at things too late after the acute events.

Dr. Wald, and because I can't remember whose hand came up first we will just take one round around the table and then I will try to watch for whose hand goes up.

Dr.Wald?

DR. WALD: I think that Hemophilus influenzae type B vaccine has had any impact on acute otitis media, I mean acute otitis media even in the heyday of encapsulated systemic disease was classed almost exclusively by non-typable organisms. So, I think that really hasn't had an impact, and the impact of the pneumococcal conjugate vaccine remains to be seen. I mean there may be a shifting of types but it may not be a very dramatic impact.

DR. RELLER: Granted. I only mentioned that as changes in the microbiology of respiratory tract infections, not necessarily with otitis media itself and as things change if you know what you are dealing with you can handle any change that comes about.

DR. WALD: Right, and so I agree with you entirely. I think that it is very important for us to perform tympanocentesis and I think that groups of children that we should be studying are children with severe disease.

I mean there are tons of arguments these days about non-treatment for acute otitis, but I think what we would all agree on is that severe disease needs to be treated and so I think those are certainly children in whom one can justify diagnostic tympanocentesis without any, I think without too much trouble. I think the double-tap design is another issue and I think it is going to be difficult to get people to do that and I don't think I would submit my child to a second tympanocentesis if they were doing clinically well. I mean that I cannot justify, but I think a diagnostic tympanocentesis for children who have severe disease which means we should load that clinical cart with young children, with children who may have had recurrent infections, with children who do attend day care and we should put in a very stiff requirement for there to be a bulging tympanic membrane which again is going to make our yield higher.

If we were going to consider doing clinical only trials my own bias would be that they only be done in

centers who have already proven by virtue of their tympanocentesis studies that they have a yield of more than 70 percent positive bacteriology. I think to do studies in places where they have not proven that they can make a diagnosis, an accurate diagnosis of acute bacterial otitis media is really to waste everybody's time and energy and is not fair to patients.

DR. RELLER: Jim?

DR. LEGGETT: To follow up on that which is sort of the reason I brought up the question during the earlier period, if you can't make a diagnosis of otitis, how do you make a diagnosis of cure of otitis at the end of therapy? That bothered me a lot and as with all these studies.

I agree with many of the things being a PKPD person myself obviously but I would sort of want to go through the handout and just make a few points that I think relate to these questions so far.

The first thing is we don't require double sampling of other infections that I am aware of except maybe endocarditis. We don't do an LP twice. We don't do paracentesis twice. We don't do urinary tract infections, and so we have got to think about that and I think I would approach drug companies with the idea of what is statistically adequate which is the third slide, and so we

give them the choice. You can either enroll 3000 people in a clinical only study or you can enroll 100 with a double tap or intermediate number with a single tap. If we do do the single tap I think that what we should do is require tympanocentesis of everybody who is called a failure either at 3 to 5 days or at 10 days which I think should be our major, at the present time, the end-of-therapy trial should really supersede the 1 month which should just sort of be to see if there is still a chronic effusion.

I, also, agree with going away from the 25 H. flu, 25 Pneumococcus, 10 Moraxella and just sort of look at those numbers in terms of what is a statistically adequate sample and that way it allows you to capture any emergent pathogens as well as really emerging resistant pathogens and allows people to look at so now we have 25 percent efflux things and we can go back and look at the MICs and find out what PKPD breakpoint might be.

Then I think in terms of the final thing for the time being it was that there was a thing about not being able to use antibiotics within the last 7 days of the last month. I think that would be another way to actually enrich the resistant population because isn't that who we have the trouble with, the more severe illness and the more resistant pathogens?

So that should actually probably I don't think require an exclusion unless the antibiotic was sort of like the day before or something, and I will shut up.

DR. RELLER: Thanks.

Any other spontaneous comments on this issue and after we go around the table I want to come back and ask Dr. Dagan his views on double tap, single tap, required taps with failures unless patient or parent refuses.

Dr. O'Fallon?

DR. O'FALLON: Remember that I am a statistician. I am not taking care of these sick kids. I, however, have been the mother and grandmother of such sick kids. So, I know a little bit about what we are talking about here.

One of the things in looking over the data that has really impressed me is the high cure rate in the natural history of the disease. The patients without bugs recover, 80 percent I think was what it was. Patients who even failed the antibiotic therapy recovered, what was it, 62 percent? It was some very high percent. So, in a certain sense the stakes in this game aren't as high as in some others because over half of the kids are going to recover with or without any kind of therapy. So, you can fight with me about that, but that is what I am seeing in the data.

The second thing that is bothering me a lot, I have been listening to you guys, and you are very worried about the promotion of drug resistant bugs, and if we are treating a bunch of kids that don't need it what are we doing to them for their future? Are we being good to them in the long run? Are we being good to the community in the long run? I think there is a big issue here more than just these children.

It is for each of these children because the drug resistance is an issue for each of these children potentially anyway, but it is, also, for the community, and I think we have got to worry about that.

Because placebo has such a large success rate I think that, and because this disease is shifting so fast, look at even the 3 years I have been on the Committee the drug resistance rate has shot up, tripled, quadrupled in just the 3 years I have been on the Committee. So, we have got a fast-changing disease here. Should we, I think maybe that makes an argument for placebo-controlled studies and it was a good idea there about having a back out. If you tap them, if they are a failure, you know, they look bad after 3 days, tap them again, find out what it is, but I think that is an important thing to do. Then you can go on and give them something decent, I mean something that you

know has a track record for whatever they. So, I think it is not a bad idea, and I lay it out for you.

I think it is important to do the randomized double-blind and concurrent, the concurrent to deal with the rapidly shifting mix of studies, I mean mix of diseases that we are seeing here.

One thing I would like to see is maybe the FDA could ask these guys now. They treated a whole lot of patients that turned out to have no bugs in their original thing. We didn't see anything about them. We never saw the information about what happened to those guys. I think they had the data in the database. I think it would be important for us to see how did it work with those guys because they just disappeared when they didn't have any of the bugs of interest. So, I would like to see that.

We know that the age groups are important. All who deal with them know that the children under the age of 2 maybe under the age of 1 are different versus 1 to 2 versus greater than 2, react differently possibly.

When we do that sort of thing we say stratify so that you have adequate sample sizes for subset analyses and so I think that type of thing has to be built into the studies for the future, and well, I have said the drug resistance.

So, those are my main points off the top of my head.

DR. CHRISTIE-SAMUELS: I agree with my colleagues. I agree with everything that has been said so far. Another point though, it is true that the FDA develops guidance with regards to antimicrobials for the United States, but as a practitioner who has been here for several years and now practicing in a part of the Third World in Jamaica for the last 2 years I would like to say that the minute something is approved here, it is also immediately marketed and used in other parts of the world, Jamaica for instance.

The problem though is that you can get drug resistance developing in those patients and because airline travel is so wonderful essentially the resistant organisms which develop in another country again become America's problem. So, I think I just wanted to say that we need to be very, very rigorous in what we do here because what you do here impacts the whole world, and then it comes right back to you a few more years later.

DR. CHESNEY: Many incredible issues, and I really, really appreciate that the FDA has asked us to be so open in this session today. I think we haven't had -- we have had discussions before, but I think this is terrific and particularly with the experts we have here.

Just a couple of brief comments. With respect to the double tympanocentesis studies, I think we have to have those because Jim's comment that you only tap failures unfortunately we know from the natural history that some of the failures have negative cultures and some of the successes have positive cultures. So, if we really want to know whether we are eradicating the organism then we have to do double studies, and then your comment, Jim about maybe we don't have to retap, but I think we learned that we didn't have to retap because of the studies where they did retap and told us that things were going to be sterile in 24 or 48 hours. So, then we didn't feel like we had to do it so much anymore.

I think the shift of organisms that Judy raised and that Ron raised in the discussion is really key and we are all very interested to see what is going to happen here. We just submitted a sickle cell center grant and one of the issues was to look at what is going to happen to those patients who are going to be on prophylactic penicillin. They are going to be on azithromycin for their chest syndrome. They are going to get the 23 valent. They are going to get the 7 valent. Who knows what is going to happen in that population, and they may be representing the extreme, but I think we have to know whether we are going

to get rid of pneumococci get rid of the resistance problem or whether it is going to emerge in new strains, and this is one of the key ways that we are going to find that out, and I think that that really leads into Dr. Marchant's comment that we really have to decide what is the question that we want to ask because the study that we do is going to be based on the question that we want answered. Do we want to know toxicity in which case it has been pointed out that we need probably lots of patients or do we want to be maintaining change, be advocates for children maintaining a susceptible population and I think that we have to try not to forget that.

So, thank you for, also, bringing that up.

DR. RELER: Dr. Cross?

DR. CROSS: We spent some time this morning expressing our concern that there was a lack of PKPD data, but I am looking at the guidance for industry and it isn't mentioned there. I am just wondering whether there is the expectation that this is naturally done in the course of things or whether this has to be stated explicitly what the expectations might be especially for different age group populations.

DR. RELER: Dr. Ebert and then we will come to Dr. Gorman.

DR. EBERT: Obviously as we go around the room it becomes increasingly difficult to add anything that hasn't already been said, but let me just say that at least my ranking of what we have been talking about as far as studies with regard to efficacy would be that at the top of my list would be double tap studies because of the issues that have already been addressed.

Next would be single tap studies at the initiation of therapy to determine what patients are in fact infected and to assess clinical response in those patients but that the clinical response be assessed at the end of therapy as opposed to at day 28.

The third would be where the patients are enrolled based on clinical findings but that taps are done in patients who fail. That would I think probably mimic the clinical scenario most closely, would limit the number of taps and then finally I think probably the lowest on the benefits would be the purely clinical studies and again for the reasons that were mentioned and the higher N that would be required.

The other issue that really gets into I think a little bit of PKPD and also the non-comparative trials would be that as Dr. Dagan mentioned certainly by giving a certain dose and looking at organisms with different MICs

we have the ability to do some PKPD analysis, but I think we should, also, consider the possibility at least in early studies of some dose-ranging studies to look not only at a fixed dose but various dose sizes especially because of the variation in the pharmacokinetics in these children as they progress in age.

DR. RELLER: Dr. Gorman?

DR. GORMAN: I think the clinical studies continue to have a role mainly for safety data generation, strictly again because the large numbers you will need to see rare or unusual safety aberrations.

Over the last 3 years I have become a connoisseur of labels which I understand is the FDA's end product. The most interesting label that the FDA has ever written is the label for Ritalin. This is my personal most interesting label which talks about the use of this drug in a total clinical care package, and I would recommend to the FDA to consider in its labeling of agents for otitis media some of the reasons why these agents fail, host factors, age less than 2, day care attendance, siblings so that the expectations for the clinicians as well as for the pharmaceutical manufacturers are there are reasons that these fail and reasons that they do not fail, reasons that they should be more successful which may start to get

around some of these other issues that we bat around as we are talking about the microbiology which is so important to this particular group.

I think the entry criteria for any clinical study that deals with microbiological cure rates has to be enriched.

One of my previous mentors did a clinical study where after tapping these patients had a 95 percent bacterial, 95 percent of the ones that he had a 90, 95 percent of the tapped ears had a bacteria identified. Those criteria if that has been implicated in other clinical studies might be adoptable by the FDA as reasons to tap people to do a primary tympanocentesis upon entry into the study.

Children less than age 2 have to be studied, and I think they have to be stratified to be at least 50 percent and perhaps 100 percent because this is the place where the drug is most likely to fail due to the host factors which we have no control over and also the ones in which we have the least PK and PD data and will need to be generated prior to these drugs being used in these populations if they have not already been used. I am sorry, if the drug hasn't been used in these populations previously then the PK and PD data has to be generated for

this particular indication.

Placebo controls. I, personally, think placebo controls will never go away, and I hope they never do, Helsinki and whoever else stands between me and my placebo controlled studies.

Even placebo-controlled study of otitis media I think there needs to be very stringent requirement that adequate analgesia and antipyresis be available for children in the placebo arm so that their long-term microbiology can be cured but their short-term pain and suffering can be relieved.

Now, on to disease resistance. I don't share my fellow pediatricians' belief that we should use, I do share that we should use the antibiotics judiciously, but I refuse to sacrifice children on the altar of drug resistance. Less than 75 percent of the antibiotic use in this country is in humans, I am sorry less than 25 percent of the antibiotic use in this country is in humans. The vast majority is in agricultural feed and veterinary medicine. So, now when you go to the antibiotic use in humans, children don't make up the majority of that either. So, if all pediatricians immediately adopted no antibiotics for anything we would probably have a very minimal impact upon the evolutionary pressures on bacteria.

Having said that I support the efforts to limit the use but I won't sacrifice children before chronic bronchitis is not treated routinely, before clinical pneumonia is not treated and before urinary tract infections are not treated, other illnesses that have incredible spontaneous cure rates and no proven clinical efficacy of antibiotics in changing clinical course.

Thank you.

DR. RELLER: Dr. Glode?

DR. GLODE: I think the reason this has been so confounded over the years is that it is virtually impossible to design the perfect study for otitis media. I would post to you even the two-tap issue which sounds great microbiologically is fraught with problems because what about drug A which has no bacteriologic efficacy and the culture is going to be positive when you do it? Of course, when do you do it, 48 hours, 72 hours, 96 hours? Is the fastest working drug the better drug, and if one drug has no efficacy and the next drug has a 2 log kill and the third drug has a 3 log kill unless you are doing quantitative cultures from the middle ear you will not be able to assess that.

So, I just think it is so difficult to actually design the right study for otitis. It may be impossible to

do that. I was wondering about the two-tap study or the single-tap study where you then take the organisms that are resistant from the first tap to the agent being studied but by what definition of resistance, a macro standard the PKPD standard that was shown today, but you know I say to the family of that child, "You child had a number of resistant organisms. So your child falls into the category of children that we would like to repeat the tympanocentesis to make sure that this organism which is more resistant is really gone," and maybe you could do that, but I think there will still be a huge argument about when the second tap should be done, and I think that there will potentially be a need for quantitative bacterial cultures which I have no idea if that is possible to do with the small volume of fluid that one gets back.

DR. RELLER: Dr. Burns?

DR. BURNS: I have been impressed today that there seemed to be two groups about which we either are or should be the most worried. The first of these I think has been well addressed, the child under 2 where we see a lot of disease. We see a lot more invasive complications and we see an innate lessened immunity to those organisms that might be invasive such as *Streptococcus pneumoniae*, and that does concern me that we don't want to neglect that

group by any stretch of the imagination.

The other group that seems to me to be important is the group in fact that does have *Streptococcus pneumoniae*. Certainly any patient who has a positive culture is more worrisome to me than one who doesn't, and it strikes me that it might be reasonable to design trials where we look at specific organisms like say, *Streptococcus pneumoniae* causes invasive disease; it has an increased risk of resistance, and it is more clinically recognizable according to some of the data that Ed O'Rourke presented.

So, perhaps it would make sense to do that initial tap and then actually conduct the study on those patients who have *Streptococcus pneumoniae* where we not only expect it to be a higher risk but also expect if we have got a good drug that it would in fact demonstrate better efficacy.

So that would be my thought process to take a very heterogeneous group of microorganisms and then focus on one that we identify as being a specific and real pathogen.

DR. MAXWELL: Not being a pediatrician most of the discussion that I heard makes a lot of sense, but I have a question to the pediatricians. Since it is clear that a good percentage of the children that develop otitis media

resolve spontaneously what I want to know is what percentage of those children that resolve spontaneously develop some adverse sequelae, hearing deficits or do they develop anything at all and if they don't develop anything at all then what is the real need to treat everybody if you have not determined that the bug has some potential for doing something somewhere down the line and so I don't know the answer to those questions and would really love to hear because it seems to me that you sort of have a natural history both into your cohorts and now, the way I would look at this I would like to know what the bug is. I would want to go after the bug, treat the bug and then see if I eradicated the bug, but you were saying that even if you identify the bug a kid might resolve spontaneously without an antibiotic and clearly we know that antibiotics are not without risk. So, it would be very difficult for me to answer this question, and I would be ideally bent to having a tympanocentesis at the beginning and at the end but I don't think that that is practical at all, and I would just like to hear the Committee address what happens to those that resolve spontaneously.

What is it that they have?

DR. RELER: Thank you, Dr. Maxwell. We have multiple, numerous pediatricians on the Committee, and who

wants to respond to her query?

Dr. Wald, why don't you start?

DR. WALD: Data have been presented today suggesting that one can identify to some extent the children who are more likely to have one organism than another but it is far from perfect. So, if you are looking at a child who has a bulging tympanic membrane you don't know which one is going to resolve spontaneously and although let us give the benefit of the doubt and say 50 percent do, 50 percent don't, and I think when we prescribe antimicrobial therapy it has a couple of purposes. You know, one is to make children better sooner and I think that isn't something to which we have paid a lot of very careful attention and I think that for those children who resolve spontaneously it is probably true that antibiotics benefit the children who are treated by virtue of the fact that they get a quicker cure than those children who eventually resolve spontaneously and then we hope to prevent complications recognizing that complications are not common but that they rarely exist and that with resistant organisms there is some suggestion that they may be increasing.

DR. RELLER: Your name, please?

DR. ROCHESTER: My name is George Rochester. I

ama statistician with the Division of Anti-Infective Drug Products here at FDA, and actually I was associated with this product being presented today.

My comments are not directed to the product specifically in any way but in general I think that our take on the FDA guidance probably needs to be seen as guidance in terms of a minimal standard not in terms of a maximum standard and that in fact I think needs to address the two probably more important issues which are data quality as well as data quantity.

The way I envision that most sponsors seem to approach drug development is in a very simultaneous fashion so that both studies are running at the same time. They get a dash to the 100-meter-yard line without any recognition of real underlying safety concerns there may be that need to be paid attention to.

So the time when the studies are designed and they are sized they are sized with very little information especially when we are talking about the new molecular entity, very little information about what kind of safety end points we are truly interested in and are really truly important. So, probably what I am thinking is that it would be more helpful if we had at least the early bacteriologic studies the studies that are specifically designed to pick

up efficacy information early and some preliminary analysis of those studies and then plan the larger probably clinical only studies with more specific interest in safety end points at a later phase so that we plan the studies adequately and we are pairing them to actually detect the things we want to detect.

The other point that I am interested in however that I haven't heard any discussion is that we have some underlying recovery rate for patients that we tap or even in other infectious diseases like community acquired pneumonia. For example, we may do blood cultures for those patients.

There is a certain rate basically even if we think that all the clinical signs or other corroborating evidence suggests a patient may really be infected with a pathogen, we do not always recover that pathogen, just doing one blood culture or just doing one tap and if you do a tap and it came back negative that does not reassure me that in fact that patient may not have a pathogen and that that patient is in fact in any other safer zone than a patient from whom I really recovered a pathogen. I haven't heard any discussion at all about that.

DR. RELER: We will ask Dr. Marchant and Dr. Patterson if they have anything to say at this point and

then we will go next to Dr. Dagan to comment on single, double with failures, etc.

Dr. Marchant?

DR. MARCHANT: I thought I would respond to a couple of things. You asked me what would I do, and I said, "Double tympanocentesis." Ellen, for example, said, "Single tympanocentesis," and gave her reasons.

Single tympanocentesis could be an acceptable way to go with good clinical outcomes but the next step in thinking about it that needs to be addressed is how big a difference are you really going to look for? What difference do you care about; what does the literature on the behavior of the disease tell you that difference is likely to be and then are you prepared to face the sample size required to follow that design?

Again, being somewhat of the devil's advocate or throwing out a little challenge, Dr. Glode said pointed out the difficulties of doing various otitis media studies and very difficult to design the ideal study and so forth, and I would throw down the gauntlet if you will and ask the question are you prepared, for example to just license drugs based on PKPD because it is hard to do a clinical study and have an outcome that is scientific or a data set that is really telling you anything and maybe we should

forget doing clinical studies. Are you prepared to do that?

I sort of throw that down as the question. Those are the kinds of questions that should be faced if you are going to scientifically approach the question of efficacy and address many of the questions that people have brought up and then the other thing is, Dr. Rochester, I believe, you asked the question of what does it mean when you get a negative culture.

DR. ROCHESTER: Right.

DR. MARCHANT: If you eradicate the organism what does it mean?

DR. ROCHESTER: Well, no, if you did a tap and the tap was negative, you didn't grow a pathogen but that does not necessarily reassure me that there are none at baseline. That doesn't reassure me that the patient did not have a pathogen just because you did not recover.

DR. MARCHANT: You mean at baseline. There is no question that that exists and when you count on electrophoresis looking for the capsule of Pneumococcus as has been done on strong middle effluence Pneumococcus was there. It is not viable and growing now, but it was there in some cases and there is no question that some of those were and there may be a few cases in which there could still be bacteria there that you didn't grow, but we know

that the number, an important point is we know that if the bacteria is there and then you don't treat it you don't effectively eradicate over 4 to 6 days that your clinical outcome on average is worse. So, on that side of the equation it is an important thing that you are finding although you haven't proved that one.

DR. RELLER: What I want to do is we will have Dr. Dagan and hear his comments and then we will come back to Dr. Patterson and Dr. Gorman.

DR. DAGAN; Look at those who were culture negative versus culture positive. We actually look at different bugs. Look at interleukins and leukocytes and at clinical response and as a group they had much less suppurative inflammatory response, have much less leukocytes and they respond to nothing very rapidly, at least no difference between the drugs for that group. So, this is for me as a group. Individuals you are right, here we are talking about group. Now, in order to explore that I would just like the Chairman to give me a few minutes. It took me 24 hours to get here, another 24 hours to go back just to hope that you can hear what I have to say.

So, if you can give me a few minutes it would be very, very --

DR. RELLER: Dr. Dagan, we ask you to come to the

microphone, please and tell us what you want to tell us.

DR. DAGAN: This is with respect to what was said around the table. I want to start just with some general stuff and I think I was very impressed by some general stuff. I think I was very impressed by the fact that you were the only one to mention that we don't know how to diagnose otitis. So, how can we know how to diagnose cure?

Years ago, at that time SKD did a study with good investigators from all over the world, the United States and Europe, and they wanted to do a study. They put us there, and they brought people from Pittsburgh who showed us a video.

Now, this is the best investigator, recognize that this is the best investigator, showed us videos with otoscopy, whatever. We all failed the test. Every single one, we failed the test, okay? So, we don't know how to diagnose otitis in general.

We miss plus or minus and definitely if you put a needle in, and you get a bug out, plus all the symptoms that is at least the most likely to be acute otitis media.

Now, it goes again for the cure. If you don't know how it is when it is there, you don't know how it is cured. So, the only way is to say that the bug has disappeared. You can add to that leukocyte count, poor

inflammatories and things like that that we are looking. So, this is one answer for sure that if you want to be sure that your sample of kids have otitis media, bacterial, take those who had all the things, but after you put the need you, also, get some pus, and it is, also, positive for culture. This is a real case of otitis media in over 90 percent of the cases.

Now, No. 2, the question of, well, I have to read my handwriting which is not that easy.

DR. RELLER: You wanted double tap versus single tap.

DR. DAGAN: I am sorry, but this is all really related because the question is why do we need double tap. This was, also, the question, why do we need double tap. We don't do it in other studies. We have to do it only in studies where we don't know how to do it in a different way. Okay, if you see a big abscess in the skin I know when it is cured, okay, but if you go a little bit wider, I have to do repeated sugar tests for diabetes. I have to do repeated blood pressure tests for hypertension. I have to do repeated cholesterol tests because I don't know how to do it without the test, and I think that if we don't know how to diagnose otitis and how to diagnose improvement the best test is to look at bacteriological eradication. So,

that is for me the most important rationale for doing that.

Now, tympanocentesis failures, and here again I apologize not being able to say it gently. The industry needs to bring 600 kids or 500 kids in no time in order to be able to be on time and go against the competitor, and to go with stringent criteria, and you do the best patients you can; you get X amount of dollars per patient if you do it appropriately and then part of doing it appropriately is when you say, "Someone has to tap the child." So, I mean there are so many doctors. Not all of them are good enough, and that is why you see all those 12 year olds or 10 year olds or whatever. They know those kids and then when they see failure they have to do taps, and they don't want to do taps. So, there are less failures because if they say, "Failure" and there is a protocol violation they don't get the money.

I am sorry to say it that strictly, but some of the investigators work for the money, not for the science, and the point is here and this is proved; that is why when you decide to have tap at failures you are going to have older kids. You are not going to have failures, and they don't have to be bothered with the taps, and that is why it is not a good idea. It is very selective cases of taps, and actually if you look at centers always selected if you go

to Alejandro Alderman in Pittsburgh he does a lot of taps at failures. You go to other centers, nobody does it. These are not failures. Okay? So, that is a very important issue.

The auditory second tap is you do it or you don't get into the study. That is a different thing. As for talking single or double tympanocentesis I think that we can deduce, we can say that kids that need most the antibiotics, the ones that are under 24 months, etc., if for them antibiotic A is good and you can show that it is at least as good as antibiotic B, it will be good for the reverse of media test, for sure because you just dilute then with more kids and more kids that don't need antibiotics.

So, if FDA comes, and this is a motion for the design, if FDA comes and says, "Okay, you do limited number of double tympanocentesis and then go for single tympanocentesis because we want the safety, etc.," but really instead of doing 500 kids, 6 months to 120 years you do 500 kids under 2. First off, we don't want to see adults if it works under 2 it works adults. Then you are going to have at least results here 10 percent difference under 2 between augmentin and azithromycin as shown by the company. It was not significant. Ten percent would be significant if

all the kids that they had were under 2.

So, this is just one way to say that you get the same type of expenses. It costs you the same, but give us patients under 2. We will be happy to extend that to older ages with otitis that are seen, okay? Rather than take above 6 months, mostly above 2 and extend it down, this is for me more dangerous. So, that is the motion in terms of if you do that single, take it only for the young children.

Then we talk about safety and this is not related but this is related to efficacy, nasopharyngeal changes are part of the safety and it is not recognized by the FDA as part of the safety because this is actually more safety than vomiting. Vomiting is tolerability. It is not safety.

Safety is an issue where by treating a child you make his situation or his surrounding situation more dangerous in the future, to be complicated and to have problems, and by changing with drugs these florae and by proposing to that child for the next infection a more resistant flora is a question of safety exactly as now in the vaccine they recognize, WHO started to recognize that changes in carriage by the pneumococcal conjugate vaccine is a safety issue because it will determine the next epidemic or the next infection with Pneumococcus.

So, I think that now some companies have started

to do it, and I think that one of the things to be done together with the double tympanocentesis is to look at efficacy or the dynamics of the nasopharynx because it follows the same type of PKPD but in a different site and you have to look at that because some drugs are making some issues, to mention for them junatopin(?) sulfa with the multi resistance, junatopin sulfa increases very impressively the penicillin resistance carriage which means next problem. So, that is another thing.

Now, talking about double tympano and single tympano without talking about what will be your end point is also inappropriate in my opinion. I think that the term "test of cure" for 28 days should be taken out because it is not test of cure. I think this is already proved, and if it is taken out then the FDA has to decide what is a test of cure.

Now, you only can offer with antibiotics what you can offer with antibiotics. The child is prone to infection. The child is going to get whatever they have in the nasopharynx next time and it is going to do more infections. So, I think the test of cure is at the end when you finish giving antibiotics that is what you can achieve with the antibiotics. The rest is not, but you can still follow it, but let us call it test of cure at the end of

treatment and let us call recurrence clinical recurrence or clinical relapse rate which is not a test of cure. So, that is another suggestion for that specific issue, and then again, the question was should we go only for Pneumococcus testing. This was double tympano. This was suggestion, okay, and we had a talk today how Hemophilus is so important and H. flu, really doesn't, I mean how Pneumococcus, H. flu really doesn't do much. Well, that did not stand with the data we saw from Pfizer.

From Pfizer they had the highest clinical failure rate with Hemophilus, not with Pneumococcus. So, if Hemophilus is not important then it should go away anyhow. So, the highest clinical failure rate is with Pneumococcus because with Pneumococcus it is resistant, okay, and it goes on and on. Hemophilus is maybe less fulminant than Pneumococcus, but it is there. If you don't respond, you do have clinical problems, and we struggle with now 8000 tympanocentesis results in our, all of us, all the bugs in our hands. we struggle to how do we describe the clinical differences between H. flu and pneumococcal patients and we don't really know how to do it. We don't have any clue how to make it clear that one is different than the other.

So, maybe when we have 20 cases it is easy. When you have 2000 cases you start to see that what you find is

this is exactly coming to the confidence interval. When you have 2000 you realize that the 20 cases were purely chance that you have some differences and that is why you have so much debate.

So, definitely H. flu is not a benign bug and therefore if you do double tympanocentesis you probably have to do it for all bugs or otherwise it is not appropriate unless you have specific questions for a specific drug or Pneumococcus and then you need to do it only on Pneumococcus and so I think that I covered what I wanted to say in terms of response, and the point is again I don't see how if you want to get the right answers, I don't see how you can go without doing double tympanocentesis. You have no answers that can be answered by the tympanocentesis. So, you did additional studies, but if you don't do double tympanocentesis in my opinion some of the real important answers are not going to be there, and we are going to get again and again things regarding the inappropriate or semi-appropriate recommendation.

The last point that is related to this is how ethical is it to do all these things, and ethics is really something very relative and it is perception and it is tradition. You do, I mean Pfizer had to present here I think altogether 2000 or 3000 cases. Each kid submitted to

a study had a lot of uncomfortable situations. If you can make 10 percent of those cases double tympanocentesis you save a lot of uncomfortable situations to 800. That is something, also, that has to be counted, but in addition Dr. Gorman is ready to accept pharmacokinetic studies.

Now, the tympanocentesis in my center is done by ENT under microscopy and it is 1 second, and you are finished. Blood is taken by my intern and they dig like half an hour before they find the vein. You know how interns do it. They have to learn how to do it. You can't be born with the knowledge how to do it, okay? So, repeated blood tests is so much more painful to the children, but this is always accepted because you know repeated blood tests plus urine and all the stuff that you submitted kids for pharmacokinetics, this is a real torture. I never agree to do pharmacokinetic studies because for many children who stand before my eyes and for hours there and we can't explain to the mother what benefit does the child get from that.

However, the mothers like when we do the double tympanocentesis studies because first it is our standard of care to do one, but in addition to get the best treatment by the best group, to get the attention if they come after 3 days with a failure we already know what is the bug. With

multi-resistance this is more complicated now because with multi-resistance stuff we can really change the drug after 3 days knowing what the child had before. We have documented in many children super infection with new bugs knowing that they did not fail. They just had a real problem, and we identified with this the children with severe problem where you don't even finish one study and they get to another infection and this kid now gets followed by a physician.

Talk about safety, we are doing routinely in our center 2000 tympanocenteses a year. Out of this about 15 percent or so are part of the study. The others are not.

In the last 6 years we had 12,000 tympanocenteses and about 2000 in studies. We didn't see even one complication. However, we see every year several complications of acute otitis media that are severe. So, I don't agree 100 percent with what you say. They come with severe mastoiditis. They go to surgery. We get how they call it, synosiventroposis(?). We get two patients in the last 5 years with abscesses, intracranial, all from acute otitis media that did not respond appropriately. So far tympanocentesis is less dangerous for us than inappropriately treated otitis media.

So, I think that again when you measure all those

things if you are used to you get different proportion and in my opinion the most of the problem if you submit the whole population to treatment that you don't know what it is it is so much ethical versus doing something in good controlled hands when you see what the child has and you can correct it at a given moment.

My ethics committee thought the last time that I submitted them a study versus azithro that it was unethical to do a study with azithro because we proved it doesn't work very well before, and they agreed finally to do it because it is standard of care still in Israel in other cities, not in our city. So, sometimes ethics is very much a relative thing.

DR. RELLER: Thank you, Dr. Dagan.

Other comments or questions not posed?

Dr. Patterson?

DR. PATTERSON: Yes, I would agree with those who think that there should be more representation of severe disease, particularly as manifested by pain and fever and that would be more associated with pneumococcal infection based on what we know about that compared with H. flu and I think that would be important for looking at rates of DRSP and also suppurative complications and so forth.

I, also, think more young children should be

included, at least 60 percent or so. I don't think that those over 2 should be excluded because based on what we heard today there may be some difference in etiology.

Perhaps H. flu is more common now in young children. Maybe Pneumococcus is more common in older children based on some of the things we have heard today and I think because Pneumococcus can cause suppurative complications we don't want to ignore that.

I think the single tap is quite important for bacterial etiology and epidemiology and so a substantial part of the application should look at bacteriology and I think the double tap is difficult to justify in many centers where it is not a standard of care and those where it is I think it is very helpful to have that knowledge, but I don't think it should be required for all the data that is submitted.

The clinical only studies I think may have a role in safety and tolerability. Somebody mentioned today about you know, did vertigo contribute to the vomiting and so there may be something about the particular disease state that could have a role in safety and tolerability. So, I think that could have a role in that.

I think there should be an emphasis on analysis by previous antibiotics within 1 to 3 months and, also, in

day care, particularly in terms of the outcome in bacterial etiology and in the clinical only study and single tap study I think it would be important to have a substantial amount of failures with follow-up tap, at least 70 percent or so, and I think a placebo study would be difficult to justify in IRB for those less than 2 years of age.

DR. RELLER: Thank you, Dr. Patterson.

I would like to comment on the numbers by organisms that were presented. My recollection is that the genesis of some of those numbers was when a particular sponsor was interested in an indication for a specific resistance mechanism or a subgroup of organisms that were resistant so that one could not get an encompassing claim that included resistant organisms where the efficacy was buried in the larger numbers as opposed to having to have for example, with tympanocentesis and even double tympanocentesis documented resistant organisms to extend to include specifically resistant pneumococci as an example.

That every study should have some of the numbers mentioned may be difficult as the ground shifts in terms of the distribution of organisms and again, I think that the getting too hidebound with specific numbers and distribution of organisms isn't largely obviated if one has the emphasis on the efficacy studies, the smaller numbers

of well-characterized patients with at least initial, if not a high proportion with double tympanocentesis along the lines that Dr. Marchant has emphasized.

Other comments, and we want to make sure, Dr. Soreth and Dr. Alexander that if something has not come out already that you raise it so that we can cover it before concluding our comments.

Dr. Jacobs had his hand up and in the good tradition of this Committee people have been very forthright and outspoken which is to the good, and there is clearly plenty of fodder for changes in the next draft.

Dr. Jacobs?

DR. JACOBS: Thanks, Dr. Reller. I would just like to emphasize the comment you made about distribution of organisms, and I think you need to apply the same standards to each individual organism based on the principles that you have heard this morning from Dr. Marchant and others that you can based on the known natural history of Strep. pneumo. You need a smaller number of Strep. pneumo than H. flu to be able to tell what goes on in a double tap study, and when you have subsets of organisms as you mentioned with resistance you again need to have each subset having the same, having a number that is statistically valid, and I think coming up with arbitrary numbers saying that you

need 25 Strep. pneumo, 25 H. flu for the drug to get an indication is not applying any of the principles we have heard about. You need to base it on what type of study it is, what age group and so on and then come up with a projection that is statistically meaningful.

DR. RELLER: Thank you.

Drs. Wald and Leggett?

DR. WALD: That sort of troubles me because it seems to me how many resistant organisms did we hear about today, a dozen resistant S. pneumoniae and a lot of, out of what 100 and they did about 166 bacteriologically proven cases? I don't think we can make a judgment on 12 cases, some of which are split between 1 day and others are getting 3 days. I can't make any judgment about that. I do think we have to have minimum numbers of resistant cases because if a study is done in an area where resistance isn't very high but the drug is going to be used nationwide where the numbers are 35 percent or 40 percent or 50 percent I don't think that we can say that the drug is approved or a good treatment for that particular indication without having had specific experiences.

DR. DAGAN: If you go for otitis media as a design as we know that about two-thirds of the beta-lactam unsusceptible bugs are, also, macrolide non-susceptible

bugs, then by having, by the approach of non-responsive otitis media you are going to increase it. You are going to have a little bit more negatives, but those who are going to be positive, are going to be more enriched with the resistance and this is based not on my assumption but on what we have as bacteriology from our studies on non-responsive otitis media, especially that first drug of choice is usually amoxi and the second one is azithro. So, when you go to non-responsive you are going to really get those two to augment the resistance.

DR. WALD: Maybe then we have to say rather than prescribing precise numbers we have to say that it has to in some way mirror what the national figures are since when we license or approve a drug that is the way it is used.

DR. DAGAN: Then be careful because the national numbers that are given to you are of all ages and of all types of bugs.

DR. WALD: They are specific.

DR. RELLER: Actually I know Dr. Wald and I if we vetted this adequately would be in agreement. The concept is that clearly there is a number of organisms that would be required and statisticians would help us if we want a specific plan for a resistant organism, but one of the things that has troubled me repeatedly and it came up in

the discussion this morning is that from a clinical standpoint an approved drug will be used in the population at large and if the studies on which we have adequate objective information are done in a population that does not mirror the one that is going to be treated when a drug is approved then we have a problem, and that came out this morning in that we had a disproportionate number of patients over age 2 and had inadequate in my view parameters of resistant organisms where we actually knew what the organism was to be comfortable that we were dealing with a distribution of organisms that is what the real world is in otitis media that needs to be treated currently and the numbers where one knows what was going on are quite small.

Dr. Wald?

DR. WALD: One more comment about the double taps because I think there are very few institutions where practically speaking that is going to be done, and again, I can talk about the discomforts of venipuncture, and you can do other terrible things to children but if a child has no symptoms referable to their ear except some residual fluid then again I think that it is hard to justify that procedure and I will just let it go there.

DR. RELLER: Thanks. Dr. Leggett or Dr. Christie?

DR. LEGGETT: A question was made about placebo controlled trials and we haven't really talked about that very much, but one thought just crossed my mind for the kids who are over 2 or the ones that are most likely going to have these more viral pathogens and perhaps we are less worried about them, one of the ways that we could capture the placebo cure rate or kids over 2, say, would be to do the placebo-controlled trial with an early escape so that if symptoms persisted at day 3 or day 4 we then proceed to that single tap. We then accumulate that as our clinical only trial group for the safety data so that you end up doing a lot fewer of these tympanocenteses and following people along, and I wondered what the pediatricians thought about something like that. That is just spur of the moment.

DR. MAXWELL: That strategy was actually used by Dutch investigators, but what you try is you try to go with not treating a bunch of people and kids and letting them hurt for a while instead of doing tympanocentesis which, also, hurts, okay. I mean you are just trading it off, but that strategy has been used by as I said, the group in Holland and I am not even sure that that would be an easy sell to patients in North America, saying, "Okay, you want to enroll in this clinical trial, and the standard of care is that we treat with antibiotics, but when a child is

still symptomatic for 2 days then we will do something?" I think it is a hard sell.

DR. RELLER: Dr.Christie and then Dr. Gorman?

DR. CHRISTIE-SAMUELS: This may be a little bit controversial, but since we are collecting so much information if they couldn't just look at the type of H. flu with regard to Hemophilus influenzae type B and I don't think it would be much of a problem to just collect vaccine efficacy, some information with regard to vaccine coverage, HiB vaccine and pneumococcal vaccine, please?

DR. RELLER: Dr. Gorman and Cross?

DR. GORMAN: To revisit the tympanocentesis, Dr. Dagan presents the local ethics issue which I find very convincing and if in my community there was a group of pediatricians that routinely tympanocentesis some relatively reasonable fraction of their children in their routine clinical care of otitis media I don't think our local IRB would object.

Dr. Dagan was not trying to imply that at all. What I am trying to say is since it is part of your routine clinical care for your patients we would have very little difficulty with you incorporating it into a study, and I hate to sound like a Luddite when I say that our IRB will not approve things like this because it is not the

purpose. It is just where is the risk/benefit in our clinical practice for the children that surround us, and last time I was able to listen to another group in another state in the United States that does routine tympanocentesis and if you are going to take routine tympanocentesis that would be an approvable study and when you said that it was local you were absolutely correct. It is a local decision.

The second question I wanted to ask, and I can ask this because I am a simple country pediatrician. Why are there no surrogate markers for infectious diseases that will help you in this case? I have heard so much about amplification of proteins for both DNA and capsid proteins. Why can't you once you know what the organism is after the first tympanocentesis, look for that organism using an amplification technique of a protein that is specific in the blood to follow its cure rate?

DR. RELLER: Dr. Cross has had his hand up.

DR. CROSS: Actually this addresses in part a comment you made earlier about the perhaps clinical outcomes correlating with the MICs and one piece of data in their Slide No. 75 was at least very intriguing that 18 of 25 of the Strep. pneumo which were either intermediate or resistant to penicillin were listed as clinical cures. i

mean something like this would argue that we cannot simply rely on in vitro microbiologic data even based on the first isolate, on the first tympanocentesis but would seem to argue that in this situation we would love to know whether or not the organism was there. So, these very limited data would argue strongly for need for tympanocentesis because otherwise you cannot evaluate this small limited data.

DR. RELLER: Thanks.

Dr. Dagan, you had --

DR. DAGAN; I would answer for the DNA stuff.

DR. RELLER: Please?

DR. DAGAN: Actually we did that study in a different way but it answered this question, and it was published years ago in JCM, Journal of Clinical Microbiology. We wanted to see if we can use a PCR for Pneumococcus in the blood to diagnose pneumococcal infections, and what we proved is the following. If you want to do a PCR for Bacillus anthracis, it is a good idea because you shouldn't carry that in your nose or anywhere else but if you take and you do PCR for something that kids carry in their nose continuously and the majority carry in the nose a little bit of DNA is enough to get in the blood and you detect it, and what we showed is we have so many true positives in terms of the PCR but false positives in

terms of infection and it was really proportionate to the age and how much you carried, and if we detected carriage we could detect up to 50 percent in the blood. So, PCR is too sensitive for a bug that is routinely carried in the nasopharynx and for what you said I would predict that 18 out of 27 or so would be clinical failures only because we know that of the bacteriological failures you only have 40 percent that are clinical failures. So, I would predict that the majority will be bacteriological failure but only 40 percent would be clinical failure and I would come exactly with that number by the way that you mentioned.

DR. RELER: Dr. Gorman?

DR. GORMAN: I would, before you sit down Dr. Dagan it strikes me that I can understand screening blood looking for pneumococcus would be very inefficient. However, once you know the specific Pneumococcus couldn't you follow titers looking at your amplification as some sort of surrogate marker for cure watching titers fall during the course of the antibiotic therapy?

DR. DAGAN: Yes and no. You could follow the titers, but you have a lot of assumptions there that you didn't prove, that you have to prove, and you didn't prove. When is the DNA the broadest proportional to the amount of the bacteria that are in the ear and not in the nose? Now,

some of the drugs are excellent for ears but not for the nasopharynx, for example, ceftriaxone. Some of them are excellent for the nose but not always for the ears or at least azithromycin is excellent to eradicate susceptible organisms both from the nose and from the ears in terms of *Pneumococcus*.

So, the point is that you are following the blood, something that is spilled off in another place. So, it could be very good for bacteremia. It could be very good in meningitis; it is easy for meningitis, but you don't know how to measure the amount in respiratory infection of DNA that gets accidentally into the blood.

DR. RELLER: Dr. Marchant?

DR. MARCHANT: There have been a number of issues raised about ethics and IRBs and tympanocentesis, etc., and because I know these issues will be discussed at great length in the future, I think there are some provocative questions to raise, and that is we should, also, ask other ethical questions, other than focusing on the individual child in an IRB situation, but, also, the question of is it ethical to do a study which is not adequate to address the question of efficacy; is it ethical to license, market or prescribe drugs without really knowing how efficacious they are? Those are also ethical questions that we should face

DR. RELLER: Thank you.

Dr.Wald?

DR. WALD: One last thing, I would say that double tap studies, which I sort of lost my train of thought before, and that is I think in some sense the most valuable studies are those that mimic clinical care, and I absolutely concur that a diagnostic tympanocentesis is essential in the bulk of patients who we are trying to learn about.

I think once we start tampering with that TM on multiple occasions we are influencing the outcome, and outcome is one of the things we are trying to judge, and so, I will just sort of keep that in mind that by tampering with the system many times that it makes a judgment about clinical outcome a little bit more difficult, and in the end clinical outcome is still an important thing. I understand bacteriologic outcome, but the things that Dr. Glode said before, you know, when is exactly the best time to tap; is an earlier sterilization substantially different than a sterilization on the fourth or fifth day, and I don't think we know the answers to those questions.

DR. RELLER: Dr. Marchant?

DR. MARCHANT: In response to the issues you raised, Ellen I would say that bacteriologic outcome is

only important because the studies that have been done have been shown that it correlates with clinical outcome. If it were not that it would not be an important outcome, but rather draw your attention that it is a surrogate that if you study enough numbers it does predict a clinical response, but that is one of the reasons it is important. It would be unimportant totally if that were not the case, but that is what the data show.

DR. RELLER: Dr. Soreth, have you heard enough?

DR. SORETH: I think we have heard enough at this point, Dr. Reller, and I guess we will take this to another public forum wherein we focus specifically on the guidance I presume at that point with votes making it clear how the guidance should go.

At this point I would say that there is not unanimity but consensus on continuing in some measure having an assessment of clinical response although we have to talk specifics in terms of the size of the trial and the kind of difference that we are trying to detect between a test drug and a control drug.

With regard to microbiological studies, again, I would say that there is more consensus on a single tap study, tympanocentesis and baseline and still a fair amount of controversy or lack of agreement with regard to an

actual requirement for double-tap studies.

Is that a fair assessment?

DR. RELLER: What I have heard today on this issue is that the agencies and alternately the sponsors and most importantly patients and practitioners would be better served by having studies of higher quality where we know what one is dealing with microbiologically and clinically and those two are complementary and that one is kidding one's self if one can make any honest with realistic numbers, any honest assessment of efficacy in the absence to tympanocentesis, and that the clinical studies have their complementary role and are important in adequate numbers especially when there are no data from other patient populations for assessing safety of a compound and that the pharmacodynamic information is of interest, but is not a substitute for clinical trials and microbiology and in patient populations where drugs may not act the same at different age groups that it is important to actually have the pharmacokinetic, pharmacodynamic data from those age groups to properly assess safety, as well as whether things all fit together in terms of efficacy, and I think that summarizes what we have concluded or the consensus view that we discussed today.

Lastly, I would say that in this issue of a study

done well that adequate numbers is the best thing to do in the public interest. Quite honestly the numbers required to do that that are dependent upon design we need expert help from our statistical colleagues to pin those numbers down and those numbers will be different depending on the quality of the study done and in general the better the study the smaller the numbers required to show the targeted differences which are a judgment call.

Have I missed anything, Dr. Marchant?

DR. MARCHANT: No, i think you have covered it pretty well, and I would just like to reinforce your last point. The clinical outcome of persistent symptoms during therapy, if you look in the literature from single studies, single centers you come up with a much lower sample size estimate of what is required to demonstrate that outcome than if you take the meta analysis that Dr. Rosenfeld used pooling multiple studies from multiple time points and multiple centers. It is just not as precise and as soon as you spread the whole game around to multiple different studies or investigators you are going to get less precision, and you are going to have less ability to show anything.

So, that is another wrinkle in the mix here of the difficulty of doing these studies, but a difficulty

that you could overcome if you really want to.

DR. RELLER: Thank you, all for your contributions. The meeting is adjourned.

(Thereupon, at 4:50 p.m., the meeting was adjourned.)

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