to consider the implications in terms of patient management.
They are asking for a claim to assist in the diagnosis, but our thinking is that does have to be viewed in the context of clinical utility. Will it be useful in the clinic? Is it sufficient to do that?

DR. AMENDOLA: I think that in order to put it a level of perspective on this problem, you really have to compare what the utility of potential use of this agent or this study could be compared to CT scans and ultrasound. I would dare to say that most patients that go an emergency room for possible appendicitis, and they have a clear cut clinical situation, a clear picture, and go to surgery right away, today in this country would probably have a CT scan. If they are pregnant women they will undergo ultrasound for diagnosis.

It was suggested in the Appendix B, there is a little comparison between CT scans and LeuTech examinations. They are pretty similar. Interestingly enough, the LeuTech has a slightly greater sensitivity, which I think is very reasonable. I would dare to say that probably if you have a comparison between the LeuTech and the $C T$ scan, the $C T$ scan will probably have a higher specificity.

I would dare to say that the main use of this agent of the study would be in those patients that are having an unclear clinical picture. And having a CT scan
which is not diagnostic, it's not either clearly positive or clearly negative that would fall in that indeterminate range of diagnosis, then I think that the LeuTech would be a very good test.

I think that that would be limited role, but a very useful role, and really help to take into consideration that I don't know if you read the quote, the literature, the bibliography in the briefing books. If you look at the literature, the accuracy, the specificity and sensitivity of especially a helical CT scan for appendicitis is extremely high. It's almost 100 percent in some reports.

I don't believe in anything there is 100 percent medicine, but I do believe that there is probably a 20 percent cases that on CT scan, done with the best technical, helical CT, IV contrast, oral contrast, or rectal contrast will fall in that indeterminant category. I think that those patients would really be the main beneficiaries of this imaging study.

MR. PUTNAM: Would you offer some comment on that?
DR. RYPINS: We actually reviewed the literature on CT, and one of the things that is important to put into perspective is that the time we were doing our first Phase 2 was really the first time that $C T$ scan was first being reported in the literature. And in fact, not to knock CT, because the results with CT are very excellent, I think what
we are doing here is to try to compare a multi-center trial with what is reported from CT centers as single institution, best data.

So really compare apples with apples, what I did was to abstract the CT literature in the last two years which is really relevant with respect to the helical CT. As you can see, the results here are excellent, the $4-\mathrm{CT}$. But our own institutional results with LeuTech are quite good as well. And this represents data that has been accepted for publication, and will be out in the September issue of The American Surgeon. It's been presented at the Southern California Chapter of the American College of Surgeons meeting.

So we are quite happy with LeuTech, holding it up against what's reported single institution CT data as well. I want to remind you that there are major disadvantages with respect to the patient undergoing a contrast rectal, contrast CT scan, oral contrast. The amount of oral contrast that needs to be ingested just prior to going into surgery in patients with positive exams. So I think that there is a role for LeuTech. And I think it will be institutionally-based.

Can I have slide number 60, please? There have not been any multi-center trials of CT. CT studies have not been subjected to the kind of blinded read process that we
are required to undergo here. Our results at a single institution can stand up against CT.

And as well, since CT is not an investigational agent like LeuTech, it has not been benefitted from an iterative testing process that has been occurring at every clinical site around the country, determining their best way of getting CT, who is going to be the best reader for CT . So I think CT has kind of an edge. But I think we stand pretty well against them.

Can I have our slide number 62, please? And this is the table from the briefing document which really shows although our study was not designed to compare CT against LeuTech, in several of the centers -- and our center is one where LeuTech was preferred generally, in the other centers that were in our trial, the surgeons there were comfortable with $C T$, and they were told specifically not to let LeuTech guide their decisions.

Many of them continued to order CT through the study. And so that's where this data comes from. Of 49 patients who had both CT and LeuTech scans, and as you can see, we did quite well. I think that ultimately where the role of LeuTech will be in the clinical environment is going to depend on the particular institutional expertise, whether the nuclear medicine expertise exists, whether the CT expertise exists. And certainly from our standpoint as a
clinical site, our surgical department prefers it.
DR. WHALEN: A follow-up question on the table you presented from the upcoming American Surgeon journal article. As I read that, it's more in the area of course of specificity that $C T$ can outshine the investigational agent. It would be clinically significant for me if you have the number at your fingertips. And $I$ think it can be culled from the data anyway on what the specificity is for operative intervention, rather than specificity for appendicitis.

DR. RYPINS: Well, in our institution this would relate to false positives with the LeuTech. The false positive rate our institution has been as I recall about 15 percent, of which half of which were patients who had no disease at the time of operation. These were true negative laparotomies. The other half had surgically indicated reasons for exploration. Some of them were listed in the overall document.

But we had one for example of a patient who had a ruptured bladder, which was a case of domestic abuse, where she had not admitted to this, and did not ever tell the surgeon that this was the case, and it picked up something like that.

We have had cases of diverticulitis presenting where the sigmoid was over on the right side. There was
peritonitis and a pelvic infection there. And so of the ones that I have looked at personally, and I have looked at the false positives in this trial, about half of those false positives would have had to go to surgery anyway. But the other half I think are patients who were true false positives from the standpoint of surgery.

DR. LINKS: A question about the instructions for interpretation. I'm struck by two things. I'm struck by the emphasis on sensitivity. I'm struck by reading the studies as positive versus negative, instead say on a five point scale where you could have gotten an ROC curve that would been introspect, told you where you wanted to operate in terms of your maximizing diagnostic accuracy. So can someone just speak to the rationale of the instructions for interpretation?

MR. PUTNAM: I can speak to them in reverse order.
I can speak to the second one. We looked at a lot of literature and other studies, particularly in this area. Some of the companies that have come here in the past with data around equivocal appendicitis have struggled to analyze the data because of equivocal interpretations. We didn't want to go down that road, so we forced a non-equivocal, if I can use that term, positive or negative interpretation. As to the instructions to the reader, I would like to ask Dr. Kipper to address that one.

DR. KIPPER: Because of the nature of the disease, we felt that it was very important to have the interpreters read with high sensitivity. We felt that missing a case of appendicitis was more harmful to the patient than misdiagnosing the case of the appendicitis with a false positive scan. So we instructed our readers, and this is how I read all of our appendicitis scans, to read for high sensitivity.

DR. PONTO: Are there any other general comments or questions from the panel?

DR. HOOVER: How do you intend for this sequence to work? Who orders this test? Are we going to get to a point where a patient comes in with a right lower quadrant pain, before we get the white count, they are going to order this? Does it have to be ordered by a surgeon? Who makes the decision that this is an indeterminant diagnosis?

DR. RYPINS: What has actually happened at our institution, on the comfort level of the surgeons, and in interpretation and the data that they obtain from these tests. And we were probably one of the first centers in the U.S. to be using labeled white cell scans for equivocal appendicitis. We, as surgeons, saw all those patients.

What has actually happened is as our institutional comfort with the examination has increased, and our experience with a very high negative predictive value, which
is what I showed you here before, we feel very comfortable as surgeons to be able to send a patient home with a negative scan.

What has actually happened in practice is it has shifted a lot, in many cases from the surgeons having to come and evaluate the patient, then ordering the scan, to where in many cases if we believe in the emergency room physician has good judgment, if that emergency room physician says that he really thinks that this is a very equivocal patient, then the discussion and the banter between the surgeon and the emergency physician is usually of the sort, then please get us a white cell scan or a LeuTech scan when we were doing the trial, and call us back with the result.

And there have been cases where we have been called in after negative scans, where the emergency room physician says the scan is negative, but I really still feel that you should come and see the patient. We do, but in many, many of those case, the scan is negative. The patient may be feeling a little bit better by the time it is over, and the emergency room physician can disposition the case without bothering us again.

That's one of the major values to me in a community hospital setting is the amount of times I have to get up in the middle of the night and evaluate patients, and
this has been a godsend.
DR. AMENDOLA: I was very impressed by the optical
quality of the images. We kind of sometimes talk about nuclear medicine as unclear medicine. But these examples, some were really very, very crystal clear to me.

Going back to my comment about CT, if you read the literature, you will think that $C T$ scan is the same. Actually, there are some cases that are really difficult. The patients have little fat in the abdomen. The patients that for some reason, we cannot give IV, sometimes are really a problem.

I don't have much experience with the pediatric population. Maybe Dr. Abramson can give us some insight, but my feeling is in children it's also not as straightforward. If we can interpret these scans is such an easy job, I think this is a great test.

DR. ABRAMSON: I think these have been excellent studies. And I understand the need to have a specific indication for this examination in the beginning. But $I$ think that we have to accept the limitations of the study. There is no study that is perfect. And the 13 percent or 15 percent false positives I think represent a group that just demonstrates this point.

There were some of those patients who had positive scans that the surgeons decided not to operate on. And some
of the diseases that these patients had, they should not have had surgery. It would be detrimental to these patients to have had surgery. So I think from the standpoint of looking at the false positive rate, and looking at the studies, we have to understand that it's not going to be 100 percent positive for atypical appendicitis.

And in those patients with false positives that you have demonstrated, there are some patients who have positive exams, but I think the surgeons decided that it still didn't fit, and so they didn't operate on them. And these may be patients who, if the clinical situation is still such that it seems very likely, perhaps should have some other study to document, for example CT , to document is it really appendicitis, or is this really something else? So I think if atypical appendicitis is an indication for the study, I see this agent as having a much more unlimited role in terms of finding areas of inflammation, which are not necessarily complicated or atypical appendicitis, but helping clinicians in other settings as well. And except the fact that even though they are positive, they are not always going to be appendicitis. I think we have to depend on the clinicians for those instances.

And I also think that the other thing that is a limiting factor in this study has to do with neutropenic
patients. And I think it should be made clear that this test is not indicated in patients who are severely neutropenic unless some other studies are done that indicate that in fact it is efficacious and will work in these patients.

DR. HAMMES: I need a little follow-up on my prior question about dose for use, I guess relative to what Dr. Abramson was just talking about. I was impressed by the anti-neutrophil effect that you were mentioning, and really haven't seen much data on what the magnitude of that is versus dose or anything.

And I guess in thinking about that, it explains to me why we see this fast RES blood clearance of this stuff. It's damaging the white cells, and they are being scavaged probably. And it explains the transient decrease in white blood cells we see in some of the studies.

And it raises the question in my mind, are these white cells that we're tagging with this antibody still functional? Or are we just imaging white cells that have already localized in the past? I guess this needs to be clear in my mind. I'm thinking in terms of the labeled indium or Technetium white cells we're used to, we're really looking at two different pictures in those two scenarios, and I would like to have some more information on that.

DR. SMITH: We have looked at the transient
decrease in the white blood cell count, and asked essentially the question that you are alluding to. What we found is that the transient decrease recovers in about an hour. The function of the neutrophils is not affected by this transient decrease at the dose we use in the clinic.

There is no evidence that we find of white blood destruction, and this is based on microscopic examination of the white cells, as well as looking for esterase in the urine. We also find that there is temporarily an increase in the radioactivity in the spleen and liver, suggesting a possible momentary increase there that is coincident with the decrease in the white cell count.

In addition to that, we have found that there is no clinical observations that would imply any negative aspect related to the decrease in the white cell count. That is over a considerable safety base that we looked at. Our conclusion is that there really is no damage to the white cells. And that any of this aspect is clinically silent.

Does that answer your question?
DR. HAMMES: This data kind of looks like global data to me. Do you have in vitro data where you label the cells and stain them, or something like that to show that there is no effect? That's what we would do.

DR. SMITH: The functional data is in vitro data,
where we looked at the actual phagocytosis adherence, and the chemotaxis. This study is reported in the literature. It was performed by Dr. Thakur.

DR. SIEGEL: I would like to comment on an aspect of that question. Earlier in the meeting there some discussion - Dr. Abramson, I think you raised the issue of whether this drug would be effective in neutropenic patients, and lacking data, obviously they have fewer neutrophil, it might not image as well. It might image. That remains to be seen.

I would simply like to point out, however, at least within the agency we have similar concerns regarding the safety data. Since the data that we have on neutrophil counts is in patients with thousands -- the counts are in the thousands, and we simply don't know what would happen in terms of the neutrophil count or function if you gave this drug whose circulating neutrophil count was 100 or 200.

But there certainly exists as a possibility, given that it is an IgM antibody against neutrophils, that one might see clinically significant changes. Until that is adequately addressed, we would anticipate that if approved, the labeling would warn about that concern.

Agenda Item: Charge to the Committee, Introduction to Questions and Initial Discussion

DR. PONTO: Are there any other general questions to the agency or the sponsor? If not, I would like the panel to find your questions. And we will start on the questions, and we'll see if we can't get through one or so before we break for lunch.

1. Characterization of pre-test probability of disease is important for several reasons: (a) a test should be evaluated in patients in whom the diagnosis is equivocal; (b) a test may perform differently in patients with different probabilities of disease; and (c) results may require different interpretation in patients with different pre-test probabilities of disease.

In the Phase 3 study under consideration, entry required some suspicion of appendicitis, but one or more atypical features. In future studies of atypical appendicitis, should entry criteria be based principally on physician uncertainty or atypical features? If the latter, please comment on which combination of atypical features would be most useful.

I think these questions are directed primarily to our surgeon and emergency room colleagues here. Would you care to open up the discussion, please?

Dr. Whalen.
DR. WHALEN: For the first question $I$ would strongly feel that it should be atypical features of a
physician uncertainty, because $I$ think it can be a much more objective arm. Physician uncertainty, I'm sure come judgment day when I have to sum up my life, I'm going to say that I'm more prone to get a three hour test at 2:30 a.m., than I am at 10:00 p.m., and it's just human nature. And physician uncertainty is just far too vague and subjective, and so I would emphasize atypical features.

For the second part of the question, if I'm emphasizing atypical features, I was very surprised in first reading over everything in preparing to come that among the symptoms was not mentioned anorexia. Since I have always hung my hat on that one, and it rarely ever steers me wrong. So if a symptom subset is to be developed, I would strongly emphasize that anorexia should be one of the symptoms. DR. BLUMENSTEIN: Well, I feel that using the physician uncertainty is only valid in the context where the physician doesn't anticipate using the experimental maneuver.

DR. PONTO: So to clarify, your comment would only be if he was left blinded to the result of the test?

DR. BLUMENSTEIN: Right, the physician knew with certainty that the experiment test results were not going to be available to make the ultimate management decision.

DR. ROTHSTEIN: I would agree with that from the standpoint of studying from a clinical standpoint, a
practical standpoint of using this as a clinician, you are using these uncertainty terms. Some are objective, a white count, a fever, versus some subjective things, where you feel the pain, the description of the studies. So I think physician uncertainty is a primary factor in this.

DR. HOOVER: That is very difficult. It is difficult because surgeons make decisions. Sometimes we might make the wrong decision. But when you have a surgeon that says I'm uncomfortable about operating on this patient with this diagnosis, and it's a very telling statement. I guess my concern is if you didn't come back to me with this positive test, and I decide not to do it anyway, because my intuition tells me that this might get better if I wait 12 hours or 16 hours, I'm not sure it's going to influence the really honest physician who says, there is something about this.

It's the art of medicine, not the science that says I'm not comfortable with this. I don't think I'll lose too much ground if I re-examine this patient or 6 hours or 10 hours or 12 hours. So the physician uncertainty part sort of depends on how the patient comes to me. If they have been screened by an emergency room physician and a pediatrician before the emergency room physician, it makes it harder on that surgeon to then say, well, I'm going to not do this. So the physician uncertainty part takes on new
meaning in that circumstance.
DR. ABRAMSON: I think part of it has to do with the experience of the people examining the patient. It's one thing for a surgical resident to say, gee, I'm uncertain, so I'm going to get this test, as opposed to an attending surgeon who has a lot of experience in dealing with appendicitis or patients who may have appendicitis.

So unfortunately, that is nothing that can be controlled. The test can't be offered only if the attending surgeon or the senior emergency room physician feels that it's a question. So I think it's very difficult to use that, because it can be used by anyone.

DR. PONTO: Any other comments? Have we satisfactorily addressed your question?

DR. WEISS: With the combination of atypical signs and symptoms, what was pointed out in the presentations is that the incidence of appendicitis changes if you have one. And that was the only requirement in this particular study. If we are thinking about future studies, could the committee comment on whether or not it should be two or greater, or 2 6? Is there any guidance in terms of additional entry criteria that might help in other types of imaging agents coming along?

DR. WHALEN: While that slide was compelling in terms of the added effect, and that's can be ignored, what
we try to do here is to judge whether something is safe and efficacious to be used in clinical practice as it exists. And I can tell you that when I have a kid who wants a Big Mac and fries, I know it's not appendicitis.

DR. HOOVER: I would also add that it's probably different between our practices. I don't do kids anymore, but when I was doing kids, we had ongoing consensus of opinion was that you would operate on the young pediatric age females before we would males, because we were taught that if they had a ruptured appendix with all the inflammatory changes that were associated with that, it might increase their chance of infertility when they got to be older.

So again, all these things come into play that make it difficult to ask an adult surgeon who is doing geriatric patients, who do get appendicitis, not very often, versus somebody who is seeing the more typical age group. So it's a problem.

DR. PONTO: So do we have a consensus then on Question 1? In looking at these questions, I was told that the agency would only like us to vote on Questions 6 b and 7 . Those are the only ones that require votes. This question does not at this time require a vote.

Since my watch says it is about noon, I guess we will break for lunch.

DR. TULCHINSKY: Can I make on comment? I comment on number one, we did use that data on "gestalt" assessment of likelihood, didn't we, to create receiver operating characteristic curves, the ROC curves. And I found them very useful indeed. Not only were they were useful, but indeed they correlated excellent with compilation as far as the number of atypical symptoms. I would favor seeing that again, personally.

DR. SIEGEL: We found those data useful in the analysis. The point of the question was really focused on entry criteria to define who gets studied. I think it's relatively cost free to collect those extra data. But I'm gathering the consensus was largely because it's a little more objective that the entry criteria ought to be based on more objective findings. I certainly agree with that comment.

DR. PONTO: I guess lunch was scheduled in an hour and a half. Okay, all of us who are going to have to try to battle the weather to get home, would like to be back in an hour. So we will reconvene at 1:00 p.m. then.

Thank you very much.
[Whereupon, the meeting was recessed for lunch at 12:00 p.m., to reconvene at 1:00 p.m.]


#### Abstract

A $\underset{\underline{T} E \underline{R} \underline{N} \underline{O} \underline{O} \underline{N} \underline{S} \underline{E} \underline{S} \underline{I} \underline{O} \underline{N} \quad(1: 05 \mathrm{p} . \mathrm{m} .)}{ }$ Agenda Item: Discussion and Questions (continued) DR. PONTO: Let's start in again. By my recollection, we are beginning on Question 2 . 2. Safety data following LeuTech administration are available on approximately 440 patients (all studies, including ongoing, and for other indications). Of these, approximately 250 comprise the experience in the appendicitis setting. The most frequently reported adverse event in all studies was vasodilatation, which was mild to moderate, but did not require intervention. There have been no serious adverse events attributed to the administration of LeuTech.


If LeuTech were to lead to serious adverse events in 1 out of 100 patients treated, there is a 1 percent chance that an event would not be detected in a study of 440 patients. If LeuTech were to result in serious events in as little as 1 in 1,000 patients treated, there is a 64 percent chance that an event would not be detected in a sample size of 440 patients.

Estimates of the incidence of appendicitis in the United States are as high as 1 in 500 per year (approximately 600,000 cases per year). Of these up to onethird, or approximately 200,000 cases per year present with atypical signs and symptoms, and could potentially be imaged
with LeuTech.
Please comment on the adequacy of the safety database given the potential for use of this product in a large patient population.

The floor is open for any comments.
DR. TULCHINSKY: Answering the question directly; I would say that the data presented were convincing. I would consider it adequate for initial clinical implementation of the radiopharmaceutical. Now with that being said, I would say it would appropriate and desirable to study it further in subgroups. Some issues have been raised in regards to neutropenic patients that would be important.

I would further that by saying if the drug were to be used more broadly, not just in a segment of patients with appendicitis, one ought to look at a younger pediatric population. We have had small number of patients as young as 5 years of age. And we certainly look for foci of infection in a pediatric population much younger than that, which radioisotopes like gallium, radiopharmaceuticals like gallium citrate are used.

So it's not inconceivable that the physicians will exercise their prerogative of practice of medicine, and apply those radiopharmaceuticals, specifically this one to a smaller age group. And I would say that it might be useful
to study those groups in a more focused fashion.
I would limit my comment at this time.
DR. PONTO: Any other comments on the safety database?

DR. HAMMES: Yes, I would agree that I think the data that we have seen is certainly convincing enough to show that this is safe for the group that we have been talking about. But I share the concern that this is going to be used in a much larger population than what we are looking at here, and continued vigilance is needed.

DR. WEISS: I just want to add, as you probably
are aware, there is an ongoing -- once something is marketed, there is an ongoing, post-market, passive surveillance program where safety information is submitted to the agency, and that information is often times used to update labeling and provide more current information.

DR. PONTO: Any further discussion on this topic?
Have we provided you with the information that you need? Then we will go on to Question 3.
3. The data regarding repeat administration of LeuTech are limited. Since repeat use of a protein product can lead to safety concerns and/or loss of efficacy resulting from antibody formation, if approved, LeuTech would be labeled as a one time administration. However, repeat imaging could be useful for patients who have
recurrent abdominal pain atypical for appendicitis.
Of 30 normal volunteers enrolled in a
readministration study, 5 developed a human anti-mouse antibody (HAMA) response with readministration. None of the 5 had "high" antibody titres (defined by the sponsor as greater than $1,000 \mathrm{ng} / \mathrm{ml}$ ) and no patient experienced adverse events related to the second administration.

If licensed, should the sponsor be required to generate additional data on repeat imaging as a Phase 4 commitment? If so, can these data all be generated in normal volunteers, or should some data also be generated in patients?

I open this up for discussion.
DR. HAMMES: HAMA is a major concern of mine. First off, we're currently looking at a couple of very promising cancer therapy radiolabeled murine monoclonal antibodies that are currently in expanded access, and look extremely promising. A HAMA titre includes the use of those agents potentially curative in a fatal disease.

I'm wondering if somehow we shouldn't concern ourselves in the use of -- I don't want to trivialize this -- use of an antibody that could potentially preclude the use in patients where it would be curative. And I think some warning to that effect would be in order. For example, it shouldn't be used without careful thought in lymphoma
patients or something.
Given that background, I think definitely the additional data on the HAMA is needed, and I think it ought to be in patients, rather than normal volunteers.

DR. STEIN: Katie Stein, Division of Monoclonal Antibodies at CDER. This antibody is an IgM antibody. Currently, all of the licensed murine monoclonals are IgG or fragments of IgG. So the extent to which the HAMA raised against this antibody would cross-react with existing products or products coming down the line that are IgG is unknown.

So if you think that is important data, you might want to recommend additional studies to look at the impact of cross-reactivity of HAMA generated by this product with other murine antibodies, other isotopes.

DR. HAMMES: It's my understanding that the HAMA response is to the FC portion, and aren't they the same in the different classes? I thought that was a species - -

DR. STEIN: No, there are unique determinants for each class for IgM and IgG. There may be some crossreacting determinants, and there may be antibodies to the mouse light chain, which would be common to all isotopes, primarily the kappa chain. But we don't have any data to date on the cross-reactivity of the HAMA raised against LeuTech.

DR. HAMMES: I would strongly suggest we get some data.

DR. WHALEN: It strikes me in the clinical reality of things that if for example a patient came in with fairly typical progression of pain, but who was afebrile and had a normal white count, and on that first setting had a negative scan, if two weeks later the patient came in with the same sort of atypical presentation, although you always don't want to get stuck with the boy who cried wolf, and you have to think about appendicitis, your clinical mindset then is, this isn't appendicitis. I don't need to do that acute test again. I need to work this up tomorrow or the next day with an upper GI small bowel or something.

I have a hard time envisioning where there are going to be legions of patients having these tests on a repetitive basis. And so to impose upon the sponsor this requirement, rather than just accepting that it will be a relatively unusual in its label for one time use, to me would be more than sufficient.

DR. PONTO: Any other comments?
DR. WEISS: Well, I also think there is a scenario where it may be not within a few weeks, which may be the same event triggering those symptoms, but even similar symptoms a year or two years, somewhere much later on where you might not be thinking the mindset of what happened.

DR. WHALEN: Even in that circumstance, again, I deal with children, so that's a certain sort of group. But if a kid came in after a year, it's going to be relatively unusual that that appendix isn't in a formalin jar by the next morning without any other tests. And the parents are going to demand it of me, despite by clinical judgment. DR. SIEGEI: Dr. Hammes, in regards to your recommendation about getting more HAMA data, you suggested that it would be best to get those data on patients. But given that comment, and even without the comment $I$ think it is reasonable to presume it would take a long time to accumulate a substantial number of patients in a clinical trial who are coming back for repeated scans. Do you have a particular concern if the data were demonstrated either in people who repeat use, and people who are healthy, who had had a prior scan as a patient, or in healthy volunteers, that those wouldn't address the questions that you are asking?

DR. HAMMES: I think a study in normal volunteers would go a long way toward answering it. But I think the second use in patients needs to be tracked, not necessarily in a study.

DR. PONTO: Have we sufficiently addressed this issue?

Then we will proceed to Question 4 .
4. The Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (February 28, 1997) recommends "the offsite image should be the basis of the definitive analysis of imaging performance in the phase 3 clinical trial." "Offsite image interpretation should be performed as in as 'blinded' a fashion as possible."

In this Phase 3 trial, the offsite readers were only provided with demographic information (age, sex, weight, height) for each patient. In such a manner one can ensure that the accuracy of reads is influenced by information in the scans, not by other predictive factors such as leukocytosis or physical findings. In actual use, scans may be interpreted in the context of other information.

In addition to the offsite (blinded) and onsite interpretations, is there a value in having offsite physicians read scans after being supplied with clinical information (e.g., presenting signs and symptoms) and/or results of other diagnostic tests?

DR. LINKS: I don't think there is a benefit to having the offsite physicians reinterpret afterwards. The whole point of the offsite blinded read is to establish the "pure" if you will, sensitivity and specificity in the absence of any other potentially diagnostic information, so
that in a base theorem sense you can insure independence of the test and any other information.

It seems to me that some of that other information is going to be population-specific, meaning site-specific. If you know for example, the prevalence in your own community, that is going to factor in ultimately to your interpretation, but not the initial interpretation of the scan.

But having the offsite physicians who don't know the prevalence in a given community or patient population try to factor that into their reading, I don't see what additional useful information is to be gained from that. So I personally don't think there is any benefit at all to having the offsite physicians reinterpret with additional information.

DR. HOOVER: I would agree with that. I think one of the things that is frustrating for us as physicians is to get back equivocal comments from a test where we want an answer. I think tell me this is appendicitis by this test, and I'm confused enough, so that I can add that to my own confusion. But it doesn't help me to get a report back from a pathologist saying I need more tissue, when he's gotten all the tissue that I have. So I agree, I don't think it's going to add much.

DR. PONTO: So if I can summarize, the consensus
is that for this particular product, the offsite and onsite, the way they were done was considered to be adequate for this particular study. Am I synopsizing the group's feeling here?

DR. SIEGEL: Obviously, what is done with this product and with any trial that is done is already done. In part we're asking this question to get a feel for what advice we should give to people who are planning trials, at least in this indication, or perhaps generalized. I was gathering from the comments that an onsite read, together with a blinded offsite read is the type of information that I was hearing you need, although sometimes people are doing informed offsite reads and other reads. I wonder if it's possible to generalize?

DR. LINKS: I think the combination of a blind offsite and an unblind onsite is a very nice combination. I think it's often interesting then to compare the two, and certainly here we did see some differences in terms of sensitivity and specificity.

Parenthetically, the sensitivity/specificity pairs from the onsite and the offsite actually fall on the same ROC curve in the data that are given here, because as the sensitivity went up, the specificity went down for the onsite. So it's not clear that they were actually on two different ROC curves. They could have been at two different
points on the same curve.
The only thing I would worry about would be onsite. Typically, the sponsor is going to pick for the blinded offsite read, the leaders, the absolute leaders, who are presumably the best at interpreting the studies. And I think it is useful then to compare that to the onsite, but only when you are absolutely certain that the onsite interpreters have been trained so that their blinded interpretation reasonably approximates the diagnostic accuracy of the offsite.

DR. BLUMENSTEIN: It seems that we also have the issue of what the purpose of this would be. I think one could think about study designs where a certain percent of the cases were submitted for an offsite open read in order to estimate or characterize the variability in the onsite versus offsite open reads. Then that would be a piece of data that could be used to document the type of performance or the difficulty in using the test, the variability in making the diagnosis.

DR. PONTO: If I may remove my chair hat here just for a moment. Being involved with this committee for a number of years, and this has come up as a general issue, and a specific issue in various products, I don't think that we can give you an exact way for each product that is going to work. I'm trying to think of an example right now, but I
think that there are cases where sequential unblinding results would be very useful, because in the real world nobody reads a study with no information at all.

In this particular one, it's an easier call than some of them. This is a yes or a no call. Some them where it's a gradation, and I wish I could think of the example, some of the products we have discussed in the past. Having some limited amount of information about the patient would more reflect the real world situation. But still keeping them blinded to critical lab results or whatever.

I wish we could give you a blanket and say every time somebody comes in, this is going to work. But I think it's going to be product-specific.

DR. HOOVER: Just as an aside on that observation, HCFA has not instructed us that we have to teach residents if they put on a requisition rule out heart attack, rule out appendicitis, the clinician won't get paid for reading the test, and the hospital won't get paid for performing the test. So you have to put down information that can justify why the test was ordered. And it has to be in the context with the patient's presenting signs and symptoms. You are going to have to put some descriptives on there, on the requisition.

DR. PONTO: Have we answered your question adequately? Okay, Question 5.
5. For patients who present with atypical signs and symptoms of appendicitis, there is a need for agents that can assist physicians in diagnosing or ruling out appendicitis. In certain subpopulations, especially women with pelvic inflammatory disease and young children, this need is especially great, because other illnesses can confound the diagnosis. Women with coexisting PID were excluded from the Phase 3 studies. Forty-eight patients (19 percent) were between 10-17 years of age, with 15 ( 6 percent) between $5-9$ years of age, and $N=10$ ( 5 percent) were older than 65.
a. Has the sponsor gathered sufficient data in pediatric and geriatric populations such that if licensed, the indicated population will be all patients who present with atypical signs and symptoms, without age restriction?

Can I open this question up for discussion of our pediatric colleagues?

DR. WHALEN: Well, I have preface this to say that surgery is the noun, and pediatric is the adjective in pediatric surgery, but be that as it may, there is at least some theoretical concern in going over this question that in a relatively rare, although not reportable case of perforated appendix in a 2 year old for instance, whose momentum(?) is so undeveloped, where the inflammation patterns are somewhat different in the peritoneal cavity,
that they might not be able to be subsumed under this "all patients without age restriction."

So I am inclined to just go with the age brackets that are the ones that were employed in the study. Having said that, although the numbers may be reasonably small in those populations, I find no reason to suspect in greater than age 5 that there is going to be such a marked difference in the pathophysiology of appendicitis that we should seek to exclude those patients.

That's the typical mindset with pediatrics, because of the testing vagaries that have been faced by all sponsors. I think it would be unfortunate if those children were deprived of this potential test, if it is to be approved.

DR. AMENDOLA: Regarding Part $B$ of the question, $I$ think that it would be very important to get more information in women with persistent PID, because that is one of the subsets that may be very important to know what the value of this test is. As we know from the presentation, this subset was excluded from the Phase 3 study.

DR. HOOVER: I would agree. I think PID is the one diagnosis and age group that would not necessarily require surgery up front. In the geriatric age group, most of the things that would be positive in this test, would
also require surgery. So it would just be one more test to help us.

DR. TULCHINSKY: I would favor the indication to specify all age groups, and not in fact zero in any exclusionary criteria. I do believe that in the past we have a good track record with that being the case. Although some concerns that in the majority of cases, we did pharmaceuticals that were as benign as far as side effects as this one is, we have pursued all ages. And the clinical practice defined later what is useable and what is not.

I don't believe in my practice experience or reading about other practices, that has been associated with concerning consequence. However, if we choose the opposite, and specify the age groups, I do believe that we will unjustifiably exclude some patients who will potentially benefit from the test.

I would rather have the medical practice postmarketing experience define these questions than us trying to chop it up in those small focus subquestions, and have the sponsor spend an enormous effort and resources pursuing them while we are not being able to use it for populations that could benefit significantly potentially. So that would be my preference, to offer it to all age groups, and let the medical practice define where they are and are not useful. DR. PONTO: Dr. Abramson, do you want to say
anything?
DR. ABRAMSON: I agree.
DR. PONTO: Any other comments?
DR. WEISS: Could I clarify for Dr. Whalen, the age group - the lowest age in this study was down to age 5 , which was felt to be the lower age of when this might be considered. You were mentioning in the very, very young. I guess I was just curious to know whether or not there would be a potential for use of this imaging product in children in the $2,3,4$, that young an age population? And if so, should we ask even post-marketing for specific information to be generated in the very, very young children?

DR. WHALEN: When the question is phrase would there be a potential? I can certainly envision there would be. While I have seen a not insignificant number of cases of appendicitis in less than the kindergarten aged child, I can't remember the last time $I$ saw one that wasn't already perforated, that didn't already have a clear, clinical picture of need for operation, maybe not for appendicitis, but of need for intervention.

So I don't think that there is going to be a very significant number of patients who will benefit from the test in that age bracket. However, again, if we judge it to be safe, and if indeed we start in clinical practice to see more kids were we can intervene sooner, then perhaps it
would have utility.
DR. ABRAMSON: I think appendicitis in very young children is confounding. It's not something that we think about, and it's a very serious disease. And so I think that this could be clinically useful, because many times these patients are ill, but really we miss it, what it is. So I too think that it should not be limited, however, and I think we should haven't have any age limitations.

I do think it would be pertinent to have some studies on younger children as they come in. It's very hard, because the numbers are very small, just as you saw in the patients who are 5-9. But I think it would be helpful to do those studies on an ongoing basis, but I wouldn't limit the age for clinical use unless something came up.

DR. SIEGEL: Dr. Whalen, in your first comment I think you said you saw no reason why the physiology would indicate that it wouldn't do as well in children, but I thought you said down to age 5 you expressed some concern about the physiology possibly being different below age 5 . Could you clarify that?

DR. WHALEN: I did say that. The clinical
behavior of appendicitis in the youngest child, which is usually the infant population, which in 20 years I've probably seen 10 cases tops, that aren't perspirants-type(?) related appendicitis cases, those kids have almost no
omentum whatsoever. The main clinical difference, which may not have any bearing upon what we are talking about in this test, is that they don't wall off their infections well. They tend to have diffuse, possibly fatal peritonitis, without the ability to wall off and abscess like the older child and adult is able to do.

So that's a distinction, but I'm not sure it's a distinction which uniquely bears upon the test that we're talking about.

DR. WEISS: The reason why I think we are sort of asking about this is because there are a lot of initiatives at the agency lately to encourage getting data in pediatric patients in all ages where it is likely to be used. And specifically one can extrapolate the safety and effectiveness from either older children or adults down to younger children if it is felt that the physiology and the conditions of the disease is sufficient similar, and the effects of the medical intervention are expected to be the same.

So I think even though a potential indication statement would not restrict ages, we are still required in the pediatric use section of the labeling, to describe what data are available, and what experience has been in the various ages studied. And if there is no reason to suspect differences in even younger than were studied in this trial,
we can put that information or alternatively, we can request such data be gathered and generated to reflect more accurately in the labeling.

So I think we're just trying to get a handle on whether or not there are potential differences such that instead of assuming that the product would work the same, we would want to actually have the data.

DR. WHALEN: If I were to put it in concise FDAese, I would be comfortable with the safety, but I would want to have demonstrated the efficacy.

DR. TULCHINSKY: Can I ask the FDA side of the table a question in respect to what has been just discussed. I am well familiar with the pediatric initiative. That's been in progress for the past five years or so. And it is mostly directed at therapeutic drugs. And it has spilled over to medical imaging agents. It is somewhat concerning as one would be thinking of effect of such a spillover on the development of medical imaging.

While it may be very reasonable and appropriate for therapeutic medications, in my mind at least it's somewhat debatable about how appropriate it is in medical imaging, especially in medical imaging with radiotracers. With tracers being stressed as a portion of the award, radiotracers, to indicate that our imaging radiopharmaceuticals are considered to be tracers, and thus
rarely affect the physiology, although this one has shown to affect some certain aspects of physiology, such as white cell count going down, which would be the only significant observation that I have been able to elicit from the data provided.

But to wrap it up I would say I would just dislike to see that initiative really snowball in holding us up with implementation of these agents, which are very benign, and have a good application into those age groups. I would say that with the physiology differences being pointed out, and that those are significant, as was also highlighted, it will probably will not affect the test implementation as it is. So I wouldn't put any holds in that reference.

DR. STRANGE: I just wanted to comment on the other end of the age spectrum. The number of geriatric patients in the study was very small, but $I$ think it is very important that agents like this be available for use in the geriatric population, because essentially all of those patients are going to present atypically. So that may actually be one of the areas where this is an extremely useful modality.
$D R$. PONTO: The second part of this question was, and I think we have addressed it a little bit:
b. If licensed, should the sponsor be required as a Phase 4 commitment to generate data on LeuTech in patient
populations such as women with coexisting PID, patients with other concurrent infections, pediatric patients?

We have address this to a certain extent.
DR. ROTHSTEIN: I would like to ask a question of clarification to my surgeon colleagues. How often do you make the diagnosis of PID concurrently with appendicitis?

DR. HOOVER: Probably less than 2 percent of the time, very, very infrequently.

DR. ROTHSTEIN: So it confuses me when you are talking about someone who has a diagnosis of coexisting PID, and you are excluding those patients. Those are patients for whom you have already made the diagnosis. It's not as if you are looking at patients whom you think have a gallbladder and you are going to scan them just in case they have appendicitis.

I guess it would be a different question, are you going to look at making the diagnosis of PID using the LeuTech scan? So I would say that we need to have more information on that. And I think they would be excluded by virtue of the fact that they have a PID by diagnosis. That wouldn't be included in any study.

DR. PONTO: I think the issue was in the Phase 3 pivotal trial they were excluded. So do we need some information on the utility of this particular group of patients, because they were excluded in the prior study.

DR. AMENDOLA: Is this test good to make a diagnosis of PID in women of childbearing age? Because I don't think we have enough data collected to clarify the issue. I think that it would be an important area.

DR. PONTO: I think issue is not can we use this to diagnose PID, but is this agent useful in the patient population with pre-existing PID. Is that the question?

DR. AMENDOLA: The key issue here is that appendicitis is a surgical disease and PID is not a surgical disease.

DR. LINDBLAD: I think part of the issue we are looking at as part of the entry criteria, women had a pelvic exam. And what $I$ can gather from the entry criteria sheet that was filled out, if they had a pelvic exam that was suggestive of PID, most likely pelvic tenderness or cervical motion tenderness, they would then be excluded from the study.

What we are looking at is trying to look at perhaps a broader patient population, where cervical motion tenderness, or tenderness in a pelvic exam would not necessarily be an exclusion criteria to get in the study. And can this scan differentiate between somebody that may have appendicitis or may have PID or may have an ovarian torsion or some other etiology for pelvic tenderness. That, from an emergency medicine standpoint, is an extremely
diagnostic challenge. And that is where we were left somewhat in a quandary with the data that we have.

DR. AMENDOLA: How many of those patients were excluded on purpose?

DR. WHALEN: While I think it would be helpful perhaps to have some of that data, in view of the diagnostic quandary that is there, and just thinking about the fact that we are talking about the vermiform appendix as a four inch tubular structure that may have white cell infiltrating to light this study up, as opposed to the right tube, which is about the same size with white cells in it, this is one instance from a clinical standpoint where unless $I$ were overwhelmed by some future study, I'm not going to be using this modality to make that discrimination, because I think there are far better techniques in my radiologist's armamentarium that are going to be able to distinguish those two.

DR. TULCHINSKY: So I would say it might be reasonable just to leave it at that, and have the clinician make that distinction, rather than going into the complicated and cumbersome pursuit. I think with the information being revealed as it is, that patients with pelvic inflammatory disease were not included in the study, thus the efficacy is unknown would be sufficient for the clinician to pick up from there, rather than having to
define that absolutely.
There are many questions I'm sure. I can think of 20 other disease in the pelvic that could potentially conflict this investigation, each of which could have a prevalence of may 0.01 percent in the population. Should we pursue them all? I don't think so. Again, I think we need to look for those answers once the tracer is in the clinical practice.

DR. SIEGEL: So you are suggesting that we should write a label indicating that this hasn't been studied in patients who have pelvic tenderness, but not ask the company to do the study, as you don't think it's important enough to get that data?

DR. TULCHINSKY: I think that would be a very fair and direct way of addressing that.

DR. AMENDOLA: I second that the recommendation that that would be the appropriate way to handle this. DR. TULCHINSKY: I would be very careful in the wording not to make it sound like you know it's not effective.

DR. PONTO: Have we sufficiently addressed Question 5? Anything else? Question 6, which will be a voting question.
6. The Phase 3 trial performance data for the aggregate blinded read, based on the surgeon's pre-scan
likelihood estimates are as follows.
(And this is the table that we were presented in the slides and in the briefing document.)
a. Please comment on whether these data support the ability of LeuTech to aid in the diagnosis of appendicitis. Please comment specifically on its utility to rule in appendicitis, and to rule out appendicitis in patients with various levels of pre-test likelihoods.
b. Do these data support a determination that LeuTech is safe and effective for use in the diagnosis of appendicitis? If so, please discuss appropriate wording for the Package Insert regarding its clinical use.

I think with respect to the last part of the question, we have already made a couple of recommendations with respect to the package insert in terms of pelvic inflammatory disease and the age. Are there any other comments, suggestions for the package insert, and comments with respect to the data and its basis to determine the safety and efficacy of this particular product?

DR. ABRAMSON: We have already mentioned neutropenia.

DR. PONTO: Oh, neutropenia also.
DR. LINKS: Personally, I'm not a big fan of accuracy, positive predictive value or negative predictive value for these kinds of studies, because they are driven by
prevalence. And I think in this study I like it, as I have indicated earlier as icing on the cake that the change in management and the looking at pre- and the post- likelihood for the physician point of view. I think it's interesting, but I don't want to make too much of it.

For example, if you look at the surgeon's pre-scan likelihood estimate in those ranges, it's sort of like when the weatherman says that there is a 50 percent chance that it's going rain today. What you do is you take all the days when he said there is a 50 percent chance, and he is good at his probabilities, and 50 percent of the time it in fact would have rained.

Yet when you look at the actual incidence of appendicitis in each of those ranges, except for the two highest ranges, and the second to highest only barely, the actual incidence doesn't fall within the range. So for example, for 20-39 percent, the actual incidence you would hope would be between 20-39 percent, but it's only 15 percent. And similarly from $40-59$ percent, it's actually only 25 percent.

So making hay about the pre-test likelihood categories I think is trying to get too much out of the data, personally. Further, just to take a couple of examples, if you look at the $20-39$ percent group, the fact of the matter is you are going to get a very nice positive
predictive value given the specificity. And the fact that the prevalence is so low means that you are going to get a very good negative predictive value, even if the sensitivity was only so-so.

On the other hand, if you look at the highest prescan likelihood group, where the actual incidence is 88 percent, you are going to get, in that high incidence or high prevalence subgroup, a lousy negative predictive value, as shown here, even if the sensitivity is good. The sensitivity is going to have to be near perfect in a group with such high prevalence or incidence in order for the negative predictive value to be decent.

So I'm not a big fan of trying to get more out of these data in the subgroupings than I think the data support. And what I'm saying is the extremes of the high incidence and low incidence, either your positive predictive values or your negative predictive value is going to be essentially meaningless, because it is so driven by prevalence, rather than the intrinsic diagnostic sensitivity and specificity of the test. And even in the intermediate groups, the surgeon's pre-scan likelihood does not match well. with the actual incidence in that group.

So my own feeling is the very, very bottom row that groups the broad "atypical" indeterminant, equivocal pre-scan diagnosis is really by far the most meaningful row,
and trying to get more out it than that $I$ think is probably pushing the data a little too far.

DR. SIEGEL: Let me just comment and ask a little more about that. Of course the predictive values are dependent on the group prevalence. And they are dependent therefore on the pre-scan likelihoods which are correlated with prevalence, but they are not fully predicted by that. So that if you look at those two groups, the 20-39, and the 40-59, those groups do have a low prevalence, 15 and 25 percent, or combined about 20 percent.

But this test then broke those down into those who have a positive scan and those who have a negative scan. And if the test did nothing, those would also both have been 15 and 25 percent. But instead with the positive scan that goes to 80 percent, and with the negative scan that goes down to 7 percent.

Now might say at 7 percent, that's a number you could look at and say you might be comfortable with not operating on those patients. Whereas if you look at the next two lines; or maybe not even observing, not admitting, if you look at the next two lines, the $80-100$ is too small, with 8 patients, but if you look at the 60-79 percent, they had a 61 percent of disease. If their scan was positive, that goes up to 86 percent, and those with a negative scan, one-third of them were still positive.

That one-third would seem to have a different implication from the 6 or 7 percent.

DR. LINKS: It's actually saying that the surgeon's pre-scan likelihood is perhaps off. And if the surgeon's pre-scan likelihood were more accurate, it might drive the decision-making in a more accurate direction, given either the positive or the negative scan. I'm just very reluctant to divvy it up based on the surgeon's prescan likelihood estimate when the data here show that their pre-scan estimates are wrong.

Now in fairness to the surgeon, they have probably never been forced to couch the data in quite these terms, and I'm sure could go back and readjust the probabilities.

DR. SIEGEL: But they correlate, the lowest and the highest. And in fact I think what you were suggesting in terms of the last line was that in fact it might be wise to exclude the low and the very high if that wouldn't be the target population. You said looking at the last line, which isn't the sum of all lines, it's the 20-80, and that's where there is some substantial uncertainty.

DR. WHALEN: With support for the sentiments that I think were just expressed, but with the simplicity of a non-cognitive specialist speaking, unless we are doing something tragically wrong in our surgical education system, this five point Lickard(?) scale had its first point being
there is no way they have appendicitis, and the fifth point was I know they have appendicitis, I can take it to the bank. And really equivocal appendicitis is the middle three.

So it's not a five point Lickard scale, it's a three point scale in which number one and number three were completely immaterial.

DR. TULCHINSKY: To add a little side to this spectrum of the discussion. To me, that was frankly a very useful table. I do like to see the ROC type of presentation, which this table provides. It is nice to see how in gestalt subgroups the test has performed. Not that I wouldn't be able to fill out those blanks myself without doing the study. I think most of them are fairly obviously. Any statistician I think could have predicted this sort of layout of data.

But to me it was very useful to see analysis displayed in this fashion. Different people of course have a different way of perceiving or analyzing the data. And I think that was to me, useful. Although I agree that for clinical purposes a much more simplified way of analysis might be just fine as well.

But I also would like to take us back to the beginning of the question. We seem to have started from the bottom and going up. I thought it was only applicable in
the bar, bottoms-up, but it seems like the rule would follow here.

The first question really was asking if the data presented was useful, will support the ability of LeuTech to aid in the diagnosis of appendicitis. I don't recall any one specifically answering that question, so let me start by saying I do firmly believe it does. And I would like to put the stake here, and maybe spin it from that point on. DR. BLUMENSTEIN: You know I have to jump into this. I love ROC curves. I really like ROC curves. But I don't like ROC curves when it is based on faulty data, because then ROC curves have the ability to put the perfume of legitimacy on data that stinks. And in this case, I don't like the sensitivity estimates, because as I pointed out before, they are in this circular thing. And I don't like the surgeon's pre-scan likelihood estimates, because I feel like they are potentially biased based on the fact that the surgeon knows that the test is going to be done, this new and fancy test, and so forth like that.

So I'm going to answer B, and I'm doing to say, yes, there is evidence that this is a safe and effective device or product for diagnosis of appendicitis, not based on the data that $I$ see in this table, but on the data that $I$ see on page 57 of the FDA briefing document.

DR. PONTO: Would you elaborate on that, please?

DR. BLUMENSTEIN: We'll get to it on number seven. So if you want to wait for that, or $I$ can comment on it now. I feel like the table at the bottom of page 57 shows exactly what went on, even though it still has some of these biases that I mentioned before about the circular definition of sensitivity and so forth, and the potential to have a bias in the pre-scan management decision. At least that table shows what happens, and shows the benefit gain and so forth.

DR. LINKS: so to put all these comments together, it seems to me that what Dr. Whalen was really saying is the five categories devolve into three. The three categories that imply a level of certainty one way or the other, are then directly related to what you are going to do management-wise. Because if you are certain at either end, you are sending them home or you're sending them to surgery. And if you are uncertain in the middle, you're going to wait and watch.

So there is a relationship between the pre-scan certainty and what you would have done management-wise prescan, and a relationship correspondingly between the postscan certainty and what you are going to do. And so the five categories of certainty devolve into three a la Dr. Whalen. And those three are then related one-to-one with what you are going to do.

DR. TULCHINSKY: Well, I think while they can be
useful in those three, the top and the bottom category, again I think provide useful data. Because we are going to see those patients in clinical practice. The top and the bottom still have some atypical signs or symptoms. So they have filtered into the study, some reason. And again, I have made a comment that life is not perfect before, and I can tell you that in our clinical practice we are going to see a lot of imperfect referral reasons. And it's useful to know how what's the efficacy of the test.

In even those patients who the surgeon might think for sure has appendicitis, but still might need some additional help. Some colleagues of ours might be assertive or sure enough that they might not be using the test, but I know a lot of surgeons who will under the circumstance, still would use the test. So why not have that sort of data?

DR. SIEGEL: What we tried to do in Dr. Lindblad's presentation and in the slides that we have to look within this population in at least three different ways, since the study collected data in those different ways was define the uncertain population. There is this 20-80 percent group, if you will that. There are those that the pre-scan plan was to observe. There are those that we outlined with 2-6 atypical findings, but excluding those with one or more than seven.

The performance actually, the statistics if you define them those three ways, are fairly consistent among the three ways of looking at the data. One of the attractive things about this way over the other has to do with the way the test is likely to used and likely to be labeled if approved, which is the company hasn't likely proposed, and unless we would hear some advice from this committee, it seems improbable that one would write up a label saying for patients with one or more or two or more atypical findings.

It is probably going to be based on wording like equivocal or uncertainty, or aid in the diagnosis. So this is the one that seemed in some sense to more directly address that sort of uncertainty.

DR. TULCHINSKY: And just as a side note to the gestalt forecasting if you like of the likelihood that the surgeons have done this study. It is nothing new obviously. We have used a very similar approach in the Piopat(?) study, where the clinician assessing for pulmonary embolism forecasted if you will, what is the likelihood of pulmonary embolism in the very similar brackets in a sense. And that was an NIH-sponsored study. It was looked over by who knows how many experts. So I think it's very reasonable.

DR. SIEGEL: We have been suggesting it for diagnostic studies. Well, this is by a 5 point, 0-20, 20-

40, in some cases there is a mark on a linear analytic scale from 0-10 just to collect the data. It's a little bit hard. I think in diagnostic studies it's been our experience that it is hard to predict a priori what is going to best define the population with appropriate uncertainty. You can say it's one or more symptoms, but you may have in there some classic cases.

If the criteria were just one or more atypical findings, you would have some cases of people that didn't even have an appendicitis. So there is obviously something in the criteria that says there is some level of suspicion, and the idea is to capture that level of suspicion. But as pointed out, just asking somebody their level of suspicion doesn't necessary get a precise read for any of a variety of reasons, both the accuracy of guessing and the other biases that may go into a trial.

So we have done it a whole bunch of ways, and hopefully in the future we will have as many options to put on the table, so each committee member who has different preferences can look at the data.

DR. TULCHINSKY: I would not imply to say that this is the only table $I$ would look at. It is not, but it's very helpful. But it's not the only piece of data of course.

DR. PONTO: Any other comments? Since this one
requires us to vote, the vote is currently on does these data support a determination that LeuTech is safe and effective for use in the diagnosis of appendicitis? And it is my understanding that --

MR. PEREZ: The consultants vote, the guest speakers do not.

DR. PONTO: I guess at this point in time we will go around the table, and each individual could state his vote. It would be a yes, it would be that it is safe and effective; a no would be that it is not. And if you want to state your reasons, please do.

DR. HAMMES: I vote yes, and I think it's unequivocal.

DR. LINKS: Yes.
DR. ABRAMSON: Yes.
DR. TULCHINSKY: Yes.
DR. PONTO: Yes.
DR. BLUMENSTEIN: We can make comments at this time? We're just voting or we're making comments.

DR. PONTO: I'm sorry, you need to vote.
DR. BLUMENSTEIN: Just voting?
DR. PONTO: You can make a comment also.
DR. BLUMENSTEIN: I would say that I'm going to vote yes, but I'm not going to say these data. And then in terms of the appropriate wording in the package insert,
that's something that takes hours to get right, but I would say something like the Table on page 57 of the FDA briefing document provides some evidence that there may be a clinical benefit to the use of this product. Yes.

DR. AMENDOLA: Yes.
DR. WHALEN: Yes.
DR. HOOVER: Yes.
DR. PONTO: Moving on to question seven.
7. The sponsor developed a questionnaire for surgeons designed to evaluate the utility of LeuTech. The surgeons filled out the questionnaire prior to obtaining the LeuTech scan. The surgeons ranked the likelihood of appendicitis, indication for other tests, and patient disposition. After the LeuTech scan results, with instructions to assume the scan result is accurate, the surgeons again filled out the same questionnaire. The shifts in patient managements, as reflected by changes in the responses on the questionnaire, were recorded. The shifts in patient management are shown below.
[The table is shown.]
Is this approach useful for assessing clinical utility?. Do the data generated by this questionnaire support the clinical utility of LeuTech?

And this again, we've been asked to vote on. Dr. Blumenstein, I think you have already prefaced remarks on
this. Would you like to comment further?
DR. BLUMENSTEIN: Yes, I don't like this
particular table as well as I like the table on page 57 of the FDA document, as I have said again. And the reason is I feel like the table on 57 lays it out so that it's more clear, at least it is to me. I imagine there might be other people who might not agree with that.

But I would also make one other suggestion on a table like the one like on 57 , is that the mode of making the final diagnosis be indicated some way within the cells. For example, in the lower half of that table on page 57, there are the four cells in upper left corner. That is, the four cells starting with 34, 2, 39, and 39. We don't know whether there was a surgical assessment there or not. It would be nice to know that, but it might make the table more complicated than it is worth.

Likewise for the row in the column having to do with surgery, we are not sure whether that was just a recommendation, or whether that was actually determined by surgery. So it would be nice to know the mode of final diagnosis.

To answer the question do the data generated by the questionnaire support the clinical utility of LeuTech, I'm not sure about that, again, because $I$ think there might be a bias because of the preknowledge that the test would be
used, and the answer from the test would be available.
DR. PONTO: Are there any other comments?
DR. LINKS: Consistently we have talked about the equivocal case. And so to me in this table, by far the most interesting is the second category, which is observed. And what you really want to know is in that category, in what fraction of the patients in that category was the decision then to send home or send to surgery. And it looks to me like in big, round numbers, like two-thirds of the patients in that pre-test category then went to either the send home or the send to surgery.

So in that sense I would say it does support. There are compelling data to support the clinical utility in the context of making a definitive change in management strategy.

DR. PONTO: Dr. Whalen, do you have a comment?
DR. WHALEN: Earlier today Dr. Hoover said surgeons make decisions. And all I could think of was the oft repeated phrase, often wrong, but never in doubt that many people apply to us as surgeons. But following Dr. Link's philosophy, I like this table with all due respect to my colleague from Chicago, because it does stratify it into those three categories.

And it does show that although we are decisive, occasionally we are wrong. But it shows to me that this is
helping us in those cases where we are wrong, where we most need the help. And so $I$ believe that it is a useful approach with this stratification of the three boxes, and that the data do support the utility of the agent.

DR. PONTO: Are there any other comments?
DR. HAMMES: I guess my problem with this is if you tell the surgeon to assume the scan result is accurate, why would anybody possibly say something other than what the scan indicates? It's essentially the scan is accurate, but I'm not going to believe it, and I'm going to do something else. It leaves a little bad taste in my mouth.

DR. LINKS: Just to respond to that. I think the difference between saying assume it's accurate, and assume it's 100 percent accurate, so $I$ image that the sort of working instructions sort of implied maybe an $85-90$ percent accuracy.

DR. SIEGEL: What you would like to do is have the data you now have from this trial, and say assuming it works this well. In fact, there is a lot to be said in this area for doing a series of trials where you first get the performance, and then use that to get data on management through either a randomized design or a design like this. But one makes the effort one can to extract data from the other trials one has.

DR. HAMMES: It seems this is kind of a poor man's
outcomes data. And to that extent I'm very happy to see it. Rather than trying to compare it some gold standard which is fallacious, like we did a couple of meetings ago on an agent: .

DR. PONTO: Any other comments? The question we are voting on them, do the data generated by the questionnaire support the clinical utility of LeuTech? Dr. Hammes, would you start us again, please?

DR. HAMMES: I vote yes.
DR. LINKS: Yes.
DR. TULCHINSKY: Yes.
DR. PONTO: I have Dr. Abramson's proxy, and she votes yes, and I vote yes.

DR. BLUMENSTEIN: Yes.
DR. AMENDOLA: I vote yes.
DR. WHALEN: Yes.
DR. HOOVER: Yes.
DR. PONTO: Question number eight:
8. If licensed the sponsor will institute a training program for end users. Ideally, the training program following licensure should be identical to or very similar to the training program utilized in the Phase 3 trail. The instruction given to both the Phase 3 and blinded readers in the training program were as follows: "read for highest sensitivity and negative predictive
value," "read with mindset of being afraid to miss the diagnosis of appendicitis."

Please comment on the potential impact of these instructions to the readers in this clinical setting. Is this type of instruction appropriate for a training program? DR. LINKS: I'll take a stab at it. I think it's interesting if you go back to the table under question six, to note that the specificities are consistently higher than the sensitivities. So if the specificities are consistently higher than the sensitivities, with an instruction to read with high sensitivity, I don't think I would want to change the instructions.

DR. PONTO: Would our surgeon colleagues care to comment on how you would like your studies read?

DR. WHALEN: Promptly and accurately.
DR. BLUMENSTEIN: I think those comments apply only if you believe the estimates of sensitivity and specificity that appear in that table.

DR. TULCHINSKY: Is that meant to say that the training program will be mandated on the users? I would like to clarify the precise implications of this. What are you saying?

DR. WEISS: Usually the experience with our imaging agents there is a training program that is used in the trial, and then it's also put in place once something is
licensed for other people not experienced with use of the product to also be able to get up to speed.

DR. CARRETTA: I think it's important to have some type of education programs for any new imaging product that comes out. I think the issue that needs to be looked at is the complexity of making the diagnosis with the new imaging agent. For example, there have been some monoclonal antibodies approved in the past few years that have been extremely difficult for a general practice nuclear medicine physician or radiologist to interpret without some type of guidance and education and training.

I think in this product, the fact that we are looking at labeled white cells is a big advantage, because we have extensive experience in using indium labeled and Technetium HMPAO with white cells in clinical practice. So when you look at a Technetium labeled monoclonal antibody that looks for infection, the ramp up time or training time for community nuclear medicine physicians is no where near as complex as in some other monoclonal antibodies that are labeled with indium or other agents.

So I think there should be some type of education program available. I think the company has spoken about having a Website, having clinical cases, having an imaging atlas, having interesting cases put up for discussion on the Website. So I think there needs to be some type of
educational program.
As Dr. Links has mentioned, if we were instructed to read with high sensitivity, and you saw the specificity data, let me simply say that you tend to look at the clinical situation as being a site investigator, and although we read as high sensitivity as we could, we still worry about false positive studies in a clinical setting.

MR. PUTNAM: I appreciate Dr. Carretta's perspective on this as a specialist in nuclear medicine. From the company's point of view, perhaps training program is not quite the right word. We had not anticipated a manclated training program. We had anticipated making information available to those who seek it, that would aid them in the use of the product.

DR. TULCHINSKY: I appreciate that comment. I was a bit concerned with the way it appears here on the paper anyway. We certainly had in the past at least one radiopharmaceutical where the training program was in the package insert. I feel that that's not appropriate. I think it's an inappropriate practice, frankly. I think it is much more appropriate to offer that on the side of the sponsor, if that's what their desire would be, which is certainly beneficial to the sponsor.

DR. SIEGEL: In fact, I wanted to clarify that, because we have had some sponsors say to us that in fact
they wanted to require a training program, because they felt that if people didn't get instructions on how to read their product, they would use the product, they would get bad results, because they used and read it wrong. And they would stop using a product.

You're not suggesting it would be inappropriate in such a setting if a sponsor wishes to do it that way, or are you in fact suggesting that?

DR. TULCHINSKY: That's a very tough question to address really. I think if the radiopharmaceutical is that difficult to read, that one has to be specifically trained in it, and it has to be required. Number one, that's a fairly patronizing approach. Number two, maybe the radiopharmaceutical should not be approved if it's that poor.

But in any event, I don't believe that requiring the training from a licensed physician prior to him using whatever radiopharmaceutical that might be in the future, I don't think that's appropriate. I think it is much more appropriate to have that training available for those who are uncertain how to use it, and not required specifically. DR. PONTO: Are there any other comments? DR. HAMMES: I think looking at the images that we saw here, this radiopharmaceutical is as clear cut as any we have. And discussions of training in relation to this one,
it's a different universe than the prior agent we are talking about. While training being available is one thing, I think this is a very clean radiopharmaceutical.

DR. TULCHINSKY: Yes, I would like to second that. The images are of very good quality, provided those were examples. Examples are always of good quality. But I do believe there is no reason to suspect the real time imaging would be much different than that. So I would strongly favor, if that's the wish of the sponsor, to provide teaching cases, I think that's wonderful. But requiring it would be in my view, inappropriate.

DR. PONTO: Are there any other comments by the committee members? The agency, have we sufficiently addressed your questions?

Then I wish to thank the committee members and the agency, and the sponsor. And this meeting is adjourned. Thank you very much.
[Whereupon, the meeting was adjourned at 2:20
p.m.]

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Food and Drug Administration, Center for Drug Evaluation and Research
Convened at Bethesda Holiday Inn, Bethesda, Maryland *** CASET Associates, Ltd., (703) 352-0091

Medical Imaging Drugs Advisory Committee

DATE(s): Monday, July 10, 2000

JMMENTS:
WORD (1) $\{3,15\}=$ Keyword (number of occurrences) \{page, line number $\}$

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