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1 to do that.

2 DR. SANTANA: But what I heard from the
3 FDA was, at least what I heard was it is okay to do
4 those studies, but those studies are not sufficient
5 enough.

6 DR. PAZDUR: Well, it really depends, you
7 know, what is the purpose of the study, are you
8 trying to determine biological activity or is this
9 a trial to demonstrate clinical benefit in a
10 situation. Obviously, you know, it is where the
11 science is at this time.

12 If somebody came to us at this time and
13 said given the science now, if we inhibit enzyme Q,
14 will you approve the drug, and this is in
15 isolation, probably that is not going to be the
16 case because the approval for a new molecular
17 entity at this time still revolves around the
18 demonstration of clinical benefit.

19 Can I say we will never accept that? No,
20 if the science evolves to that point where we
21 believe that this is a very reliable surrogate
22 endpoint and we are very comfortable in accepting
23 it, then, we would be happy to revisit that
24 situation.

25 DR. SANTANA: Sharon.

1 DR. MURPHY: Actually, I have been taking
2 a list of a few comments, if I may, that really
3 lead us from the general discussion back to the
4 topic that Charlie and Mike had, may I? Just a
5 few.

6 DR. SANTANA: Go ahead.

7 DR. MURPHY: The first one, on the end of
8 this discussion, the hoped for, I would say, is
9 that yes, sometime there may be flexibility to have
10 different endpoints for approval, even surrogate
11 endpoints, but as far as the surrogate ones, I am
12 sure there would be need to be validation of their
13 relevance before they could be accepted, and I am
14 not sure there is that in all the cases yet or in
15 many, but I hope we will have novel endpoints for
16 some biologics especially, Joe, because they are
17 not going to be judged by the usual parameters of
18 efficacy. That was point one.

19 The second point I would like to make, I
20 think as we are focusing too much--and I am picking
21 on Charlie now, which is not something I am known
22 to do--I like to think about and to see
23 differences, as you clearly demonstrated in outcome
24 and reviewing the ASH abstract about between adults
25 and children, but today, I think we are spending

1 too much time on whether the responses to treatment
2 are similar or different, or the responses in terms
3 of the toxicity profile. That is missing the point
4 I think of what we are talking about because we
5 expect the responses to be different, and that is
6 why we want to do pediatric studies.

7 So, why are we talking so much about
8 showing differences in responses, that really has
9 nothing to do with the mechanisms of action or
10 safety or the disease process. There are always
11 going to be differences, and we shouldn't focus on
12 what the survivals are. That is looking at it from
13 the wrong direction, I would say, for this
14 discussion.

15 DR. SCHIFFER: I put that up as a point.
16 Let's say we are going to stick something in the
17 middle of a complicated ALL regimen because we
18 think it has T-cell specificity, let's say 506U,
19 the cytotoxic, turns out to be the case.

20 Can we do a combined trial in children and
21 adults? Maybe we can, maybe we can't, but I think
22 that is why I brought up that point as to whether
23 or not we could combine those data in that fashion.
24 I am fairly confident we could in AML and probably
25 the lymphomas, but I think that important abstract

1 raises that point.

2 I don't think it raises that point on an
3 STI or an MLL inhibitor, for example.

4 DR. MURPHY: Okay. I understand better
5 the point now. You are clearly right, and it
6 really goes to the feasibility, then, of doing
7 trials, should we even decide that they should be
8 the same or different.

9 Then, turning to I think an answer perhaps
10 to one of the first questions here about
11 lymphoblastic disorders, what general principles
12 could be used, I would like to echo and support
13 Michael's suggestion that at least for the
14 molecularly defined ALL subgroups, if they exist in
15 adult and pediatric, they are the same.

16 Also, I like the notion for the 40 percent
17 or so of ALLs not otherwise specified between
18 adults and children lacking a specific marker, call
19 them the same, and the same way with refractory
20 ALL, recognizing the importance of learning from
21 that subgroup, still for drug testing, call them
22 the same.

23 In that way, it is striking that if we
24 said that at the end of the day as a proposal, that
25 would be a nice parallelism to the AML. That is

1 exactly what we said for AML. I think that is
2 consistent at least, it may not be right, but at
3 least it is consistent.

4 DR. POPLACK: Just one question about
5 that, Sharon, and that is, what do you do if a
6 product is available that targets a specific
7 lesion, which may be only 3 percent of the
8 population, and one possible indication is
9 refractory ALL, which is a much larger percentage,
10 I believe, who makes the decision as to what the
11 indication is for that drug from the company?

12 A company is more likely to want to go for
13 an indication where they are going to be
14 encompassing a wider group of individuals rather
15 than necessarily for a small and specific track, so
16 I guess when the rubber meets the road, how do you
17 deal with that type of a classification?

18 DR. MURPHY: I am not going to answer
19 that.

20 DR. SANTANA: Sharon, do you want to
21 comment on that?

22 DR. MURPHY: No, I have no idea.

23 DR. HIRSCHFELD: I am going to offer an
24 absolutely uninformative, but correct answer, and
25 it is case by case.

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1 DR. SANTANA: Charlie?

2 DR. SCHIFFER: Companies want their drugs
3 approved, and they will pick a target where they
4 perceive it is simpler to demonstrate efficacy,
5 and, of course, that is why you see all these
6 approvals in desperate situations both in adult
7 solid tumors.

8 To get back to Rituxan, I think that is a
9 great example of what happens when a drug gets
10 approved for a very, very narrow window in terms of
11 what happened subsequently. You know, it is now
12 called vitamin R for better or for worse, it is
13 incredibly widely applied for every B-cell
14 lymphoproliferative disorder. In some cases, it is
15 clearly for worse.

16 But watching, almost looking at the ASH
17 abstracts is sort of fascinating for Rituxan, watch
18 the original Phase I, the so-called pivotal trial
19 and stuff, and then the numbers that have
20 increased, not only in numbers of patients, the
21 numbers of abstracts, but numbers of diseases, and
22 then it is going to do this, and, you know, get
23 back to where it belongs.

24 But it is a nice model actually of
25 watching what happens when a drug with possible

1 wide applicability gets out there and see how it is
2 used, and companies recognize this.

3 DR. SANTANA: Dr. Boyett, you had a
4 comment?

5 DR. MURPHY: Can I have my last one?

6 DR. SANTANA: I gave you an opportunity
7 before, Sharon.

8 DR. MURPHY: Sorry.

9 DR. SANTANA: That's all right. Go ahead,
10 go ahead. I am teasing you, Sharon. Go ahead.

11 [Laughter.]

12 DR. MURPHY: Last point. In reflecting on
13 some of the comments made about prognosis and I
14 think, Michael, you last slide where you said you
15 were lumping, your summary slide, where you had the
16 very good prognosis, hyperdiploid and TEL-AML
17 subgroups of ALL, and you said something like,
18 well, nobody would ever study these or do trials in
19 these because standard treatments are so successful
20 anyhow, and it struck me that they are curative,
21 but they are not necessarily satisfactory
22 treatments.

23 When you get to the point of Charlie's
24 point, it raises this issue of how can we develop
25 novel therapeutics for disorders that really have

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1 small populations, because really, I mean, you
2 know, if we could encourage that, and it may be
3 through the RAID program or other things because
4 these are not economic targets by any means, but we
5 would really want to prioritize the types of trials
6 for those rare subgroups even if they are highly
7 cured with standard treatment, because if you could
8 replace it with something that is specific, that
9 would be very, very important.

10 So, I don't think we should just focus on
11 the poor prognosis things either, we have to
12 prioritize the good things even if it is like
13 Wilms' tumor where everybody is cured. If you had
14 something that reversed imprinting in the WT-1
15 gene, hey, that would be cool.

16 DR. BOROWITZ: Just to comment on that,
17 Sharon, I think it gets back a little bit to the
18 ethical questions that were raised earlier and also
19 just some observations I have made as a
20 non-therapist outsider looking at the workings of
21 the Cooperative Oncology Groups, is that there is a
22 much greater reluctance to back off from successful
23 therapy than there is to try something new.

24 I don't discount the possibility of doing
25 it, but from a realistic perspective, I think

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1 people would have to have a very compelling reason.

2 DR. MURPHY: I agree with that.

3 DR. BOROWITZ: So, I think if somebody
4 comes up with a TEL-AML one specific agent, it will
5 first be tried in those patients who happen to
6 relapse with TEL-AML1. Of course, based on my
7 comments before, the reason they relapse may have
8 nothing to do with their TEL-AML1, and we may lose
9 an opportunity to have a good drug, but I don't see
10 a really good way around that.

11 DR. SANTANA: Dr. Boyett has had his hand
12 up for a while.

13 DR. BOYETT: This is a question for Dr.
14 Borowitz.

15 In your classification scheme for
16 childhood B lineage ALL, you didn't mention
17 anything about children diagnosed under the age of
18 one, and while we are sitting here trying to
19 discuss how we want to treat children with the same
20 type of genetic diagnosis of ALL as adults or vice
21 versa, it seems that in the pediatric oncology
22 community, infants with B lineage ALL under the age
23 of one similarly diagnosed are treated differently
24 than those over the age of one.

25 DR. BOROWITZ: I think you are quite

1 right. I think all of the answers are not in, in
2 that group. Clearly, a portion of that has to do
3 with the very high frequency of leukemias
4 associated with MLL rearrangements, and if you take
5 those patients out, in general, children with ALL
6 under the age of one will do a little bit better,
7 but I think it is also true that they don't achieve
8 the success rate that older children do, and
9 conversely, older children with MLL rearrangements
10 don't seem to have the same dismal prognosis of the
11 infants.

12 So, I guess what I am saying is to some
13 extent, the things we know about biology explain
14 some of the differences, and so to the extent that
15 we have biologically driven classifications of
16 therapies, that will take care of part of the
17 problem, but I think you are quite right that that
18 doesn't take care of all the problem, and infants
19 are a particularly knotty problem as anyone who has
20 dealt with them knows.

21 DR. SANTANA: Dr. Poplack.

22 DR. POPLACK: I think what Michael was
23 discussing previously is sort of a conundrum
24 because to some extent, I agree practically. If
25 you get something that is good for a specific

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1 subtype of ALL, cytogenetic subtype, that happens
2 to be doing well with the conventional therapy, it
3 is again a nightmare for the clinical trialist to
4 try and come up with a way of demonstrating it.

5 On the one hand, you can say how is it
6 ethical to consider doing that, changing midstream,
7 however, you can make a strong argument to the
8 contrary, which is that we know that many of the
9 therapies that cure kids are associated with
10 toxicities, and if you have something that is more
11 specific, that may have fewer toxicities, we may be
12 ethically bound to study that versus the
13 combination therapies that may cure all, but
14 have--you know, the cure is not in a sense the
15 final answer here, it is being able to cure with
16 minimal toxicity, I guess, that will be the
17 ultimate barometer.

18 DR. SANTANA: I think we want to get back
19 to the questions. Malcolm, do you have a final
20 comment?

21 DR. SMITH: I want just to clarify the
22 comment about surrogate endpoints. Someone earlier
23 today, one of the first speakers, had a slide about
24 the difference between childhood cancer treatment
25 and some of the adult cancer treatment and cure

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1 versus palliation.

2 I would encourage us as we talk about
3 surrogate endpoints and alternative endpoints, that
4 our bar not be lowered, that what we are looking
5 for is cure and agents that improve the cure rates
6 with improved toxicity profiles.

7 So, while palliation may be particularly
8 attractive in some adult populations, it is much
9 less attractive in a young childhood population.

10 DR. SANTANA: I would support that
11 statement.

12 DR. SCHIFFER: It is not attractive in
13 adult populations.

14 DR. SANTANA: Because there is no other
15 option, right.

16 **Questions to the Committee**

17 DR. SANTANA: Okay. Let's get to the
18 questions. We are on Question No. II for
19 lymphoblastic leukemias. A. What general
20 principles could be used to relate lymphoblastic
21 malignancies in adults to lymphoblastic
22 malignancies in children?

23 I think Sharon took an answer to this by
24 in essence saying that for the individual defined
25 subgroups, they are really the same, and they

1 should be treated the same; for the refractory,
2 they should be considered the same; for the not
3 otherwise specified, they should be the same.

4 So, in essence, the parallel she was
5 trying to propose as a comment was that they all
6 should be grouped together as the same and looked
7 at the same in terms of therapeutic trials.

8 Does that summarize well your comment,
9 Sharon?

10 DR. MURPHY: Just the last sentence is
11 that it leaves its parallel between what we said in
12 AML and what we are saying in ALL.

13 DR. SANTANA: That is correct.

14 DR. MURPHY: Which is nice symmetry,
15 whether it is correct or not.

16 DR. SANTANA: Does anybody else want to
17 comment on that? Yes.

18 DR. ARTHUR: I had a question. One of the
19 things that Dr. Borowitz brought up is that
20 probably for all intents and purposes, T lineage,
21 ALL should be considered the same in adults as
22 children, and I don't know if you considered that.

23 DR. MURPHY: I didn't say anything about
24 that. Let's discuss it more.

25 DR. ARTHUR: I was going to ask you if you

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1 thought it was the same. I am deferring to you.

2 DR. MURPHY: Well, I don't want--I mean
3 probably not exactly.

4 DR. POPLACK: I am not sure it is, and I
5 think that what you mentioned is we don't have a
6 lot of information. There are some studies that
7 have been done which show that there are clearly
8 differences in the translocations that are seen in
9 adult T cell and pediatric.

10 There is not a lot of data to this extent.
11 I think it is somewhat early to make that as a
12 definitive conclusion, but I thought you said given
13 the information we have at the moment, there is not
14 a lot of--

15 DR. BOROWITZ: I would agree with that. I
16 don't think we have any compelling data to suggest
17 that they are different, and the way I would
18 approach that is the same way I approach the 40
19 percent of children that we really don't know.

20 Absent clear differences between adults
21 and children, my bias is to say they are the same,
22 but certainly we know enough about T-cell leukemias
23 to know that there are some different mechanisms at
24 play and maybe those will turn out to be important,
25 and they may differ between adults and children and

1 we just don't know, but until we know, my bias
2 would be to say that they are the same.

3 DR. SANTANA: Steven.

4 DR. HIRSCHFELD: I would just try to
5 clarify the point by stating that what we are
6 asking advice on is whether studies should be done,
7 not whether the diseases are the same or whether we
8 should approve it for children given that we might
9 approve it for adults, but should we investigate,
10 and that should be the trigger.

11 DR. SCHIFFER: At least in ALL, it is more
12 likely that most compounds will be going from
13 children to adults first rather the other way
14 around. There might be an exception, maybe STI,
15 but certainly there are more children.

16 DR. POPLACK: But they are doing better,
17 and I think from the point of view of it is hard to
18 do a study to demonstrate that the addition of a
19 new agent is really going to make a difference in a
20 disease where your figures are so good overall in
21 terms of success rate.

22 So, it is easy to do that in populations
23 obviously where patients are doing quite as well.

24 DR. SANTANA: Any other comments? Let's
25 do subpart B. Which of the following adult

1 diseases has a pediatric counterpart and what is
2 the basis for making this association?

3 [Fire alarm.]

4 DR. SANTANA: I guess we need to evacuate
5 the room for a while.

6 [Recess.]

7 **Perspectives on Lymphomas**

8 **Stefania Pittaluga, M.D.**

9 DR. PITTALUGA: I am Stefania Pittaluga,
10 pathologist, working at the NCI, together Dr. Lane
11 Jeffrey in the Immunopathology Section. As a
12 pathologist, I will go through the extensive review
13 of the WHO classification entity by entity.

14 I will skip the first ones here that we
15 have already discussed.

16 [Slide.]

17 As everybody in the audience knows, the
18 WHO classification is based on a similar principle
19 as the real classification that was developed, and
20 is based upon identification of disease entity
21 based on morphology, phenotype, cytogenetic data,
22 and clinical presentation.

23 [Slide.]

24 The precursor to B-cell neoplasia, B and T
25 has been already discussed. Among the mature

1 peripheral B-cell neoplasm, I highlighted here that
2 the nodal marginal zone B- cell lymphoma and
3 follicular lymphoma have been described and can
4 occur in children, while most of the others, as
5 everybody have already mentioned, they occur
6 predominantly in the adult population.

7 It is of interest that although they are
8 relatively rare compared to what we see in the
9 adult population, there are some distinctive
10 features that kind of separates them from what we
11 see in the adults.

12 [Slide.]

13 In the more aggressive category of the
14 diffuse large B-cell lymphoma, Burkitt
15 lymphoma/Burkitt cell leukemias, those are the ones
16 that occur more frequently in children, as has been
17 already pointed out, although they represent only 1
18 to 2 percent that we see in adult populations.

19 [Slide.]

20 Regarding the mature peripheral T-cell
21 neoplasm, aggressive NK-cell leukemia can occur in
22 children, young adults especially in Japan,
23 although here we don't see them that frequently,
24 and hepatosplenic gamma delta T-cell lymphoma can
25 also occur in the young population, as well as

1 subcutaneous panniculitis-like T-cell lymphomas.
2 Although again these are very rare in the adult
3 population, I just want to point out that they can
4 occur also in children.

5 The largest group of peripheral T-cell
6 lymphoma that occur in the children population is
7 represented by anaplastic large cell lymphoma or T
8 and null cell phenotype, which is a systemic
9 disease contrary to the cutaneous primary
10 anaplastic large cell lymphoma.

11 It is of interest that this particular
12 type of lymphoma has been grouped in the past
13 within the diffuse large cell lymphoma, and has a
14 distinctive clinical behavior and characteristics.

15 [Slide.]

16 Regarding Hodgkin's lymphomas, the three
17 highlighted are the ones that we see in children,
18 as already pointed out. They are similar to what
19 we see in adults. I just want to mention that the
20 nodular lymphocyte predominant in Hodgkin's
21 lymphoma is a B-cell lymphoma and has
22 characteristic morphology phenotype not expressed
23 in CD15 and 30 contrary to the classical Hodgkin's
24 disease, and it is described and seen in children,
25 and has similar characteristics as we saw in adult

1 population, predominantly occurs in young males and
2 has similar clinical features.

3 [Slide.]

4 I will just briefly mention the pediatric
5 follicular lymphoma because we believe it is a rare
6 lymphoma subtype that occurs in children at 1 to 2
7 percent. It has some distinctive features that we
8 can see, contrary to what we see in the follicular
9 lymphoma in adults.

10 They usually present in the head and neck,
11 the majority of them, but they can involve other
12 sites, particularly GI tract or gonads. The other
13 difference is that usually they are of Grade II or
14 III. They are higher grade than what we see in the
15 adult population.

16 They are usually BCL-2 negative both by
17 molecular studies, as well by protein. There is a
18 predominance male over female at 3 to 1, and 85
19 percent of those present with Stage I or II
20 disease, and they achieve CR in 75 percent with a
21 low relapse rate.

22 Because of all these features, we believe
23 that pediatric follicular lymphoma might present a
24 distinct entity that is different than what we
25 observe in the adult population.

1 Similarly, there are some difference in
2 the nodal marginal zone. We just collected a
3 series at the NCI, and it is of interest that they
4 also have features that are morphologically
5 distinctive from nodal marginal zone in adult
6 population. They tend to have very good clinical
7 behavior.

8 [Slide.]

9 Regarding the more aggressive type, and I
10 refer specifically to the Burkitt
11 lymphomas/leukemias, in children I think that the
12 issues on the borderline with large B-cell
13 lymphoma, and therefore, the category that is
14 called Burkitt-like, that is an overlap, a
15 continuum of progression between Burkitt lymphoma
16 and large B-cell lymphoma is less of a problem than
17 what we have in studying the adult population in
18 which the percentage of diffuse large B-cell
19 lymphoma is much broader and much larger, and
20 therefore, this overlapping in the group that we
21 call Burkitt-like or Burkitt with the typical
22 features is much more a problematic entity, if it
23 is an entity.

24 [Slide.]

25 Therefore, the question that we have often

1 is Burkitt-like lymphoma, should it exist, and if
2 we have Burkitt-like lymphoma, should those be
3 included with the diffuse large B-cell lymphoma or
4 should those be considered as morphologic variant
5 of Burkitt lymphoma.

6 This is one of the issues that has been
7 hotly debated at the WHO classification.

8 [Slide.]

9 Now, we have several points that point
10 towards the fact that Burkitt's and Burkitt-like
11 lymphoma, they are both derived from a germinal
12 center, they both can show follicular colonization,
13 the cells in both entities resemble the dark zone
14 of the small blasts of the germinal centers.

15 The fact that there is detectable high
16 rate of somatic mutation in immunoglobulin gene
17 reveals that those cells might have been exposed to
18 antigen. The positivity for BCL-6 and CD10
19 strongly supports the idea that those are indeed
20 derivation of germinal center.

21 [Slide.]

22 Therefore, the additional parameter that
23 we use to define Burkitt-like lymphoma, which as I
24 mentioned I think is more of an issue in the adult
25 population, they are similar to Burkitt, they show

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1 usually greater variation in nuclear morphology.

2 One of the features that they try to
3 tighten it up, the group, is to show that there
4 should be a proliferative rate, which is kind of a
5 surrogate marker for the expression of c-myc, that
6 the proliferation rate should about 100 percent.
7 They are usually CD10 positive and are almost all
8 BCL-2 negative.

9 Of course, cytogenetics or molecular
10 genetics demonstrated a c-myc translocation is
11 desirable for diagnosis, and to put this group in
12 this category, and this morphologic variant is also
13 more commonly seen in immunodeficiency states.

14 [Slide.]

15 Therefore, in the WHO classification, the
16 term "Burkitt-like lymphoma" is retained and is
17 considered to be a variant of Burkitt lymphoma, and
18 the major criteria that we will use to put this
19 into the category of Burkitt's is the intermediate
20 morphology of the nuclear features, the presence of
21 c-myc translocations, and as I said, as a surrogate
22 marker, the high proliferative fraction.

23 Therefore, if you have a lesion which has
24 shown 99 percent of high proliferative rate, it is
25 going to be put within this category assuming that

1 the marker I mentioned before are such.

2 [Slide.]

3 The Burkitt lymphoma therefore will be
4 divided with the morphologic variants, which
5 comprise the classic Burkitt lymphoma, atypical
6 Burkitt or Burkitt-like, and Burkitt's with
7 plasmacytoid differentiation, which is most
8 commonly seen in HIV-associated condition.

9 Moreover, there are subtypes related to
10 the difference in the clinical presentation and
11 genetic aspects, as well as the characteristic of
12 the c-myc translocation, and those are what are
13 known as the endemic form, the sporadic, and
14 immunodeficiency-associated.

15 [Slide.]

16 The second of the lymphomas that I would
17 like to discuss, and that is the anaplastic large
18 cell lymphoma, which is basically represented like
19 the paradigm of the process that we use to define
20 disease entities in the real specification.

21 In fact, this disease was originally
22 described based on morphology and the sinusoidal
23 growth, and antigenic phenotype, which was the
24 presence of the CD30, and therefore was called CD30
25 positive or K-1 lymphomas.

1 The molecular pathogenesis led to the
2 identification and actually translocation was
3 earlier described, and it was associated what at
4 that time was called malignant histiocytosis
5 originally, but the molecular pathogenesis brought
6 in the possibility of detecting the translocation
7 by RT-PCR and further, the development of a
8 monoclonal antibody against the ALK-1 protein give
9 us new diagnostic tools to better define the
10 borders of this disease.

11 [Slide.]

12 It is predominantly a disease that occurs
13 in children or young adults, and it is of interest
14 that most of them, they occur as a nodal disease,
15 however, cutaneous involvement could be present, as
16 well as at extranodal sites.

17 In frequency, it presents with B symptoms,
18 which is less predicting the clinical outcome in
19 contrast to other non-Hodgkin's lymphoma, and
20 moreover, although it has an aggressive natural
21 history, they have a good response to chemotherapy.

22 [Slide.]

23 This is just taken from a publication by
24 an international study group on a large series of
25 267 cases of anaplastic large cell lymphoma, which

1 they showed that the predominant population is
2 present is in the first two decades of life.
3 Plotted here is the presence of the translocation,
4 its variants, or the expression of ALK-1. It
5 actually reflects exactly the same distribution
6 meaning that the majority of cases in children are
7 ALI-1 positive.

8 [Slide.]

9 That leads to the survival curves, an
10 overall survival of 154 of those patients in which
11 it clearly shows that the ALI-1 positive children
12 actually have a much better behavior than not the
13 one that we observe in the ALK-negative cases.

14 [Slide.]

15 Therefore, in conclusion, the ALK-1 ALCL
16 is probably a distinct disease entity of its own,
17 that this should be separated from the ALK-1
18 negative cases, and I mentioned, this is of
19 particular interest to this group since this occurs
20 predominantly in children and young adults.

21 Thank you.

22 DR. PRZEPIORKA: Thank you, Dr. Pittaluga.

23 Our next speaker, Dr. Hutchison for
24 Upstate Medical University.

25 Is there a question for Dr. Pittaluga

1 while Dr. Hutchison is getting ready?

2 DR. BROSS: Just a brief question. I
3 understood there was some new molecular marker for
4 prognosis in large cell lymphoma, and I believe
5 this is more in adults, and I think that came from
6 the NCI, but I can't remember the source.

7 Are you familiar with this?

8 DR. PITTALUGA: I am sorry, which one?

9 DR. BROSS: A molecular marker for
10 prognosis in large cell lymphoma.

11 DR. PITTALUGA: In the marker array data
12 from Dr. Stulz's group, the diffuse large cell
13 lymphoma segregated in two major clusters. One is
14 poor prognostic indicator which has inactivated
15 B-cell phenotype versus the one that resemble more
16 the germinal center phenotype, there is a series of
17 genes that have been named, however, I don't know
18 which one is being tested at the moment frankly.

19 The one that they have always chosen in
20 presentations are genes that we usually follow in
21 those particular cases like CD10, BCL-2, BCL-6,
22 IRF-4. So, those are known pattern already within
23 pathology, that might segregate between the two
24 groups, but I don't know of new genes that have
25 recently come out.

1 DR. BROSS: I think I am supposed to give
2 my name and affiliation. I am Peter Bross. I am
3 with the FDA DODP.

4 Thanks.

5 DR. PRZEPIORKA: Any other questions?

6 Dr. Hutchison.

7 **Robert E. Hutchison, M.D.**

8 DR. HUTCHISON: I think Dr. Murphy already
9 summarized what I have to say, and that is that
10 Hodgkin's disease is probably the same, and
11 non-Hodgkin's lymphoma is probably different
12 between adults and children.

13 Dr. Pittaluga basically said some of the
14 things that I am going to say, but I am just going
15 to go through this and show you some pictures and
16 some numbers.

17 [Slide.]

18 As you know, lymphomas are derived by
19 lymphoid cells which come from the lymph nodes and
20 the extranodal lymphoid tissues, which include B
21 cells, follicular center B cells, mantle cells,
22 interfollicular T cells, and a whole host of
23 subtypes of all of those, and so it is not
24 surprising that we have a lot of different types of
25 diseases.

1 [Slide.]
2 Hodgkin's disease has been classified
3 pretty well for a long time since probably really
4 the fifties, although the classification that we
5 currently use goes back to the late sixties.

6 There is really four main types, which we
7 will go into in a minute. Although non-Hodgkin's
8 lymphomas are almost equal in number in children,
9 there are really a lot of different types of
10 non-Hodgkin's lymphomas to deal with.

11 This is a partial listing, and I think in
12 the WHO classification, there are either 28 or 30
13 classes, in the REAL, there is 26.

14 [Slide.]
15 That makes a problem when you try to
16 summarize anything about non-Hodgkin's lymphoma,
17 they are very diverse.

18 I just pulled out some raw data. This is
19 not official data, but this just happens to be the
20 types of cases that the Pediatric Oncology Group
21 has enrolled on studies in the last three years,
22 and you can see that nodular sclerosis Hodgkin's
23 disease is the most common with small, non-cleaved
24 cell Burkitt and non-Burkitt lymphoma being second,
25 lymphoblastic lymphoma being third, and diffuse

1 large B-cell lymphoma and anaplastic large cell
2 lymphoma each tied in there.

3 Other forms even of Hodgkin's disease are
4 relatively uncommon compared to the rest of these,
5 and you don't see any of the rare 26
6 classifications in this at all.

7 [Slide.]

8 This is just Hodgkin's, and the only
9 reason that I show this slide is to point out that
10 his work was based on the anatomic presentation of
11 the disease, it had nothing to do with molecular or
12 phenotypic or even microscopic morphology, but his
13 observations have borne out very well over all
14 these years.

15 [Slide.]

16 Hodgkin's really is four types - mixed
17 cellularity, lymphocyte depleted, and nodular
18 sclerosis is the most common and lymphocyte
19 predominant.

20 [Slide.]

21 All of which have in common one thing
22 which is the Reed Sternberg cell which is shown
23 here in a variety of ways. The Reed Sternberg cell
24 is something which we have only recently started to
25 know a little bit about, and the paradigm is

1 evolving that it is derived from, a B cell,
2 probably a follicle-center B cell which has
3 undergone some sort of crippling mutations or some
4 sort of abnormal process in that it will not
5 produce immunoglobulin RNA.

6 [Slide.]

7 Hodgkin's disease incidence is actually
8 relatively flat throughout life. It peaks in young
9 adulthood and in old age. In young adulthood, the
10 peak is nodular sclerosis Hodgkin's, which tends to
11 occur in young women with mediastinal involvement,
12 but it does occur in males also.

13 Lymphocyte depleted Hodgkin's disease is
14 the one which tends to occur in older people, and
15 actually mixed cellularity and lymphocyte
16 predominant are relatively flat throughout age, so
17 this is a disease which does occur in both adults
18 and children.

19 I think I am going to skip over a lot of
20 this stuff, and if anybody has questions about it,
21 we can get back to it, and I will go right to the
22 non-Hodgkin's lymphoma, and like I said, we can
23 address some things if there are questions.

24 [Slide.]

25 I have summarized all the 26 kinds of

1 non-Hodgkin's lymphoma into basically seven groups,
2 that is, the small lymphocytic and related
3 lymphomas, the mantle cell lymphomas, Burkitt's
4 lymphoma, lymphoblastic lymphoma, follicular
5 lymphomas, large B-cell lymphomas, and the
6 peripheral T-cell lymphomas including anaplastic
7 large cell lymphoma.

8 [Slide.]

9 With clear classification schemes, we
10 really need phenotype to be precise in our
11 diagnoses, and we can use phenotype not only to
12 classify lymphomas, but potentially in the future
13 to identify targets, such as alkaline expression
14 anaplastic large cell lymphoma, BCL-2 expression in
15 a variety of lymphomas, not necessarily related to
16 BCL-2 translocations.

17 [Slide.]

18 Non-Hodgkin's lymphoma, I pulled this out,
19 it is a relatively recent reference based on SEER
20 data, and I was a little bit surprised to see that
21 in the U.S., that diffuse large B-cell lymphoma is
22 by far the most common at the current time. I had
23 thought actually that follicular lymphoma was the
24 most common, but according to this reference, it is
25 diffuse large B-cell lymphoma.

ajh

1 Now since in adults, NHL is approximately
2 15 times as common as it is in children, this is
3 largely going to be adult data. The interesting
4 thing is that the high grade lymphomas are
5 relatively uncommon in adults, but these constitute
6 virtually all of the lymphomas in children.

7 [Slide.]

8 In children, the published data shows this
9 to have about 5 to 10 cases per million children,
10 whereas, the adult data is per 100,000, so there is
11 at least a log difference in the incidence. This
12 is just to show in the POG in the last three years,
13 the same set of data that I showed before.

14 The distribution is almost equal between
15 small, uncleaved Burkitt's and non-Burkitt's,
16 lymphoblastic, large B cell, and anaplastic large
17 cell lymphoma. So, these are the four predominant
18 players in pediatric lymphoma.

19 [Slide.]

20 Burkitt's lymphoma is really a fairly
21 homogeneous thing, which is associated with a
22 translocation involving c-myc and one of the
23 immunoglobulin genes. There are really multiple
24 types of Burkitt's lymphoma, that is, there is the
25 endemic Burkitt's, there is the sporadic Burkitt's

1 that we see in pediatric patients mostly. There is
2 also those Burkitt's which are associated with
3 immune deficiency, either HIV or post-transplant,
4 which are a little different in terms of the
5 breakpoint and the insertion site of EBV.

6 The reason this may be important is that a
7 lot of the data, a lot of the biologic data on
8 Burkitt's lymphoma actually come from those which
9 are EBV associated, which tend to grow well in
10 culture, whereas, the sporadic Burkitt's, which do
11 not have EBV, do not like to grow in culture, and
12 there is not a lot of cell culture data on those
13 cases.

14 Another kind is large B-cell lymphoma, and
15 this is a disease which we saw is the most common
16 in adults, and it is one of the more common in
17 children, but there may be differences between
18 large B cell found in adults and children, too.

19 I am not sure, there is not a lot of good
20 data on large B-cell lymphoma in children, and as a
21 matter of fact, we did not even know the
22 distribution of T and B cell phenotype in large
23 cell lymphoma in children until paraffin reactive
24 monoclonal antibodies became available in the late
25 1980s. There is not a lot of flow cytometry data,

1 there is not a lot of biology data, and so whether
2 or not this is the same as large B-cell lymphoma in
3 adults can be easily argued.

4 These tend to have a higher proliferative
5 fraction, not as high as Burkitt's, but approaching
6 that. They tend to have c-myc expression by
7 immunohistochemistry.

8 Burkitt-like lymphoma, again to reiterate
9 what Dr. Pittaluga said, is a borderline between
10 Burkitt and large cell. Some of them are actually
11 variant Burkitt's, some of them are probably large
12 B cell. My feeling is that in this spectrum, that
13 there is a great spectrum between Burkitt's and
14 large B cell, and then really dividing them into
15 three categories is not necessarily accurate, but
16 it is the best we can do at this time.

17 [Slide.]

18 Now, just to mention the rare lymphomas in
19 children - small lymphocytic lymphoma just like CLL
20 that Dr. Borowitz mentioned is exceedingly rare in
21 children, but it has been described.

22 [Slide.]

23 There are six or seven cases that I saw in
24 the relatively recent literature. Three of those
25 had a consistent translocation. My guess is that

1 this is not the same thing we are going to see in
2 adults because I haven't seen that translocation in
3 adult small lymphocytic lymphoma. So, it is a rare
4 disease, does exist.

5 One thing I learned as an early pathology
6 resident is that every disease occurs in every
7 organ at every age if you look hard enough, but
8 generally, those are rare.

9 [Slide.]

10 Follicular lymphomas are probably the most
11 common of the rare lymphomas in children. They are
12 very common in adults, but they do occur in
13 children also.

14 [Slide.]

15 Most of these, as we have already heard,
16 are of the larger cell type, either mixed or large
17 cell. Most of the ones I have seen have been large
18 cell.

19 They really constitute up to about 1
20 percent of pediatric lymphomas, but I think they
21 are different diseases. If you look at the
22 literature critically, very few patients ever
23 relapse with follicular lymphoma in the pediatric
24 population while virtually all patients in adult
25 populations relapse, and that alone makes it very

1 different.

2 Those few who actually have failed therapy
3 in the world's literature have progressed to
4 diffuse large B-cell lymphoma, and what we may be
5 seeing is a follicular and diffuse large B-cell
6 lymphoma, which may behave more like, in some
7 cases, like diffuse large B-cell lymphoma. There
8 are not enough cases to really know.

9 [Slide.]

10 Marginal zone lymphomas, which are
11 probably the lowest grade of the adult lymphomas,
12 do occur in children. At least half of the cases
13 which have been reported have been in HIV cases,
14 but there seems to be an increased smattering of
15 reports of these things occurring in
16 non-immunosuppressed people.

17 [Slide.]

18 Those rare cases tend to mimic the ones in
19 adults, in the GI tract and the spleen and the
20 salivary glands, a few in the lung, but they are
21 also quite rare.

22 [Slide.]

23 Mantle cell lymphoma, which we greatly
24 fear in adults, I don't think occurs in children.
25 I have never seen it and I have never seen it

1 reported, and someone else might know of that. I
2 thought I saw a case once, but it turned out to be
3 a cutaneous B lymphoblastic, and it wasn't.

4 [Slide.]

5 Now, T-cell lymphomas other than
6 anaplastic large cell lymphoma and lymphoblastic
7 lymphoma are rare in children, just like they are
8 uncommon in adults, and there is not a whole lot to
9 say about them. I will skip over that.

10 [Slide.]

11 Lymphoblastic lymphoma, we have heard a
12 little bit about. It is actually quite common in
13 children, and it is turning out to be one of the
14 lower prognosis forms of non-Hodgkin's lymphoma in
15 children as we get better results with the B-cell
16 lymphomas.

17 [Slide.]

18 Anaplastic large cell is the one that most
19 pathologists have been interested in, in children,
20 and we think that we can generally identify this
21 one now with the monoclonal antibodies, and there
22 are some actually good polyclonal antibodies, but
23 most people are using monoclonal ALK-1 to identify
24 the so-called "alkalomas."

25 This is a characteristic case. This is

1 actually about half of large cell lymphomas in
2 children. Now, the fact that ALK-1 positive
3 anaplastics do better than ALK-negative anaplastics
4 may or may not be related to the disease itself.

5 There is an age thing in there, and most
6 reports of anaplastic large cell lymphoma include a
7 spectrum from adults to children, and with most of
8 the ALK-positive ones being under age 35, and most
9 of the ALK-negative ones being over 30. So, it is
10 very hard to compare survival data between patients
11 who have a median age of 20 or 18 and a median age
12 of 50 or 60.

13 We really don't know. We are looking at
14 this in the COG to see if there is a difference,
15 and we haven't demonstrated any difference between
16 ALK expression or not.

17 [Slide.]

18 We do know, though, that most anaplastic
19 large cell lymphomas in children express ALK. This
20 is CD30 positive large cell lymphomas, and the
21 majority of them express ALK. That has been
22 published in a variety of ways. That particular
23 piece of data is raw, though.

24 [Slide.]

25 So, non-anaplastic peripheral T-cell

1 lymphomas are rare. Anecdotally, people say they
2 don't do well, and that is probably true.

3 That is basically it. We have four types
4 of lymphoma that we are dealing with.

5 DR. PRZEPIORKA: Thank you.

6 **Discussion**

7 DR. MURPHY: Aside from admiring the
8 pictures of Lugarno [ph] and the masterful
9 encyclopedic classification now with the REAL and
10 the WHO, neither of you commented--perhaps you
11 would--on whether you want to come down on how the
12 Rule should be applied, which is why we are here
13 today, and I am wondering if I heard the subtext
14 here that each of these real entities is really
15 different from each other, and really they should
16 all be considered separately, or what words would
17 you put in your own mouths as to how to apply the
18 Rule to these entities? That's the question,
19 right?

20 DR. HUTCHISON: Before I sit down, since I
21 have a microphone in my hand, I will give my view
22 on that if I can.

23 I think that a drug that is derived or
24 produced for follicular lymphoma does not apply to
25 children, and when it is derived and developed for

1 CLL, it does not apply to children. I think that
2 we really don't know in the other categories if
3 they are the same diseases or not, and we probably
4 have to assume that large B-cell lymphoma,
5 anaplastic large cell lymphoma, lymphoblastic
6 lymphoma may be the same, and the Rule may apply in
7 those.

8 DR. PRZEPIORKA: Dr. Pittaluga?

9 DR. PITTALUGA: I would think that some of
10 them like Burkitt's lymphoma or lymphoblastic are
11 more common in children, are more homogeneous, and
12 I think that those are entities that they are
13 similar to the one that we see in the adults,
14 although much less frequently.

15 There might be some subtle differences
16 within the Burkitt's in different groups, but I
17 think that overall clinically there is behavior
18 much more similarly.

19 Regarding the anaplastic large cell
20 lymphoma, I think it is very interesting the point
21 you raised that the majority of the ALK-negative,
22 they are in the adult population, and therefore, it
23 might be that this is indeed a disease that is
24 strictly confined to children, and we might not
25 have an adult counterpart although there are

1 sporadic cases that are ALK-positive in the adult
2 population, but those are really anecdotal, so it
3 is kind of the reverse that we have seen in most
4 other lymphomas.

5 The other entities, I think they are real
6 and they exist, and they affect mostly the adult
7 population, and there are definitely biological
8 reasons why these occur. I would agree that I
9 would not use drugs that you use for adults
10 translating them into children, and follicular
11 lymphoma, for instance, relatively rare, we believe
12 that indeed there is a distinct disease, and has
13 nothing to do with what we see in adults, and it
14 might be that even the nodal marginal zone, which
15 is very rare in adults, but it also might have some
16 distinct features that are typical of children.

17 DR. MURPHY: I think it just emphasizes
18 the practical aspects and the difficulty of
19 applying the rules here, because of the plethora of
20 real different types of non-Hodgkin's lymphomas,
21 now readily recognizable by expert clinicians and
22 hematopathologists, each one very rare.

23 DR. PRZEPIORKA: Dr. Schiffer.

24 DR. SCHIFFER: We will trade you the
25 mantle cells for almost anything. In the ones

1 where there may be overlapping, particularly the
2 small non-cleaved, where we have so much trouble in
3 adult oncology distinguishing it between
4 Burkitt's-like and large cell, and there is also
5 probably a major therapeutic implication with
6 regard to that distinction, as well.

7 Should these be defined as whether they
8 are myc-mutated or not? Is there sufficient data
9 to make that distinction, and if so, would those be
10 analogous to the Burkitt's or the pediatric
11 experience, because again with the small,
12 non-cleaved in adults, if we use these short
13 intensive regimens, we cure 50 percent, we don't
14 cure 90 percent, and some of it may be who is doing
15 the treating, but I don't think so, I think it is
16 really more that there may be heterogeneity.

17 DR. MURPHY: Just on that point and not
18 belabor it, I mean it is how you define it, I
19 think, and how strict you are in making
20 distinctions for protocol eligibility between
21 Burkitt-like or pure monomorphic Burkitt c-myc
22 translocated, and because I think a lot of adult
23 trials where this distinction between large B cell
24 and Burkitt-like is a lot harder than it is in kids
25 where we have a purer entity, I think maybe that is

1 why the cure rates aren't as high. There is a
2 mixture of cases, as well as differences in the
3 host.

4 You know, again, we shouldn't focus too
5 much on the outcomes, it is whether the entities
6 are alike, and during the WHO Clinical Advisory
7 Committee meetings at which I participate at the
8 Airlie House, there was long arguments whether even
9 Burkitt-like would stay in the classification.

10 Enough experienced adult clinicians argued
11 yes, it has to because it does have therapeutic
12 implications, that it survived being otherwise
13 thrown out. It was a close call.

14 DR. SCHIFFER: In the adults, there are no
15 good data about what percentage of those are myc
16 mutated.

17 DR. MURPHY: Right, that is why I think
18 they are mixed up.

19 DR. SCHIFFER: Right, but which may, in
20 fact, eventually define which side of the line they
21 go on.

22 DR. MURPHY: Right.

23 DR. SCHIFFER: How many of the children
24 have myc mutations with small, non-cleaved?

25 DR. MURPHY: It is not 100 percent.

1 DR. HUTCHISON: I can answer that. We
2 don't know. You mean myc-translocated or
3 myc-mutated?

4 DR. SCHIFFER: I am sorry, I meant
5 mutated.

6 DR. HUTCHISON: You mean translocated
7 because myc tends not to mutate.

8 DR. SCHIFFER: I am sorry, I meant H-14 or
9 its variant.

10 DR. HUTCHISON: Right, and one of the
11 problems with pediatric lymphomas is its sample
12 size tends to be very small and it is has not been
13 traditional for primary treating institutions where
14 the diagnosis is usually made to do cytogenetics on
15 Burkitt's. It is actually kind of hard to do it.
16 You have to be very fast and do direct unstimulated
17 preps to get a karyotype off of Burkitt's.

18 We don't really know, and we have proposed
19 in the COG now that we have some paraffin-reactive
20 FISH probes to look at that, because we really
21 don't know. I think most of the data is really
22 based on cell cultures and on L3 leukemias even in
23 the adult population.

24 I do know that myc is activated and
25 expressed in virtually all pediatric B-cell

1 lymphomas including large B cell, so you can't use
2 that.

3 DR. SCHIFFER: I wonder then, that it
4 might be premature until these data are forthcoming
5 to lump the adult and the pediatric small
6 non-cleaved on the assumption that these data will
7 be coming soon.

8 DR. HUTCHISON: If I may, in the adult
9 lymphoma, large B-cell lymphoma tends to respond
10 pretty well to CHOP, and that is what people use
11 usually, and the Burkitt's lymphomas, some people
12 feel that they need more aggressive therapy, and
13 that is why you want to separate it.

14 In the pediatric groups, the tendency now
15 is to treat all B-cell lymphomas the same with
16 Burkitt type therapy, that is the trend, and that
17 may be over-treatment for adult large B-cell
18 lymphoma. We don't really even know if adult large
19 B-cell and pediatric large B-cell lymphoma are the
20 same.

21 DR. PRZEPIORKA: Dr. Borowitz.

22 DR. BOROWITZ: I just wanted to bring up
23 another kind of lymphoma that I didn't hear
24 mentioned and to just raise the issue of how much
25 of a parallel we should draw between adults and

1 children, and that is the lymphoproliferative
2 disorders that arise in the post-transplant setting
3 or in immunodeficiency disease.

4 My own bias is that whatever you call them
5 histologically, they are more alike than they are
6 different, and I think that that is a group of
7 tumors that we should also include in the
8 discussion because they are different, on the one
9 hand, from Burkitt's lymphoma, and on the other
10 hand, from typical large B-cell lymphomas.

11 DR. MURPHY: It is hard to tell when they
12 are lymphomas.

13 DR. BOROWITZ: That is certainly a
14 reasonable point, and it is not always clear when
15 they are lymphomas, although they have outcomes
16 that are often similar.

17 DR. PRZEPIORKA: Other questions? Dr.
18 Hutchison, what about the histiocytic diseases, are
19 they are adult diseases we should be looking for
20 that could be used to tip off when to look for the
21 pediatric histiocytic diseases?

22 DR. HUTCHISON: You know, it is hard to
23 say because they are all so rare. The main
24 "malignant histiocytosis" that was thought to be
25 fairly common in children is actually anaplastic

1 large cell lymphoma now, and there are several
2 different kinds of histiocytic proliferations in
3 malignancies, you know, viral-associated
4 hemophagocytic syndromes, there are histiocytic
5 lymphomas which are not anaplastic large cell
6 lymphoma, but they are exceedingly rare, they are
7 less than 1 percent probably. It is very hard to
8 know what do with those, I think.

9 I mean the Histiocyte Society exists
10 partly to determine what to do with these, but we
11 don't see them very often, and almost all of the
12 results are anecdotal, to my knowledge.

13 Questions to the Committee

14 DR. PRZEPIORKA: Let's move on to the
15 questions then, for lymphoma No. III. What general
16 principles could be used to relate lymphomas in
17 adults to lymphomas in children?

18 Dr. Murphy, would you like to take a
19 recapitulation, if you will, of your previous
20 recommendation?

21 DR. MURPHY: I think the general
22 principles are the ones that underlie the REAL
23 classification, and the WHO that followed it, which
24 is it is a combination of criteria that define
25 entities. It's immunophenotype, it's morphology,

1 it's cytogenetics, it is sometimes clinical
2 features, and those are the ways to subclassify
3 them.

4 I think we are all in the general
5 agreement that the common ones seen in children are
6 not common in adults, although they occur rarely
7 and vice versa, and so I think we have to fall back
8 on the most modern paradigms for their
9 classification and use those rather than come up
10 with something entirely new, but what would it be,
11 I have no idea.

12 I mean we have got to, just as was pointed
13 out here, use these criteria.

14 DR. PRZEPIORKA: Dr. Smith.

15 DR. SMITH: So, there is Burkitt's, there
16 is lymphoblastic, and there is diffuse large, and
17 there is anaplastic, and those four, if there were
18 an adult indication for one of those four, then, it
19 would warrant studying in children, and follicular
20 and the other classifications that don't occur in
21 children, would not necessarily warrant a pediatric
22 evaluation.

23 DR. MURPHY: I have to agree with that.

24 DR. PRZEPIORKA: And Hodgkin's?

25 DR. MURPHY: Hodgkin's is the same.

1 DR. PRZEPIORKA: We have kind of answered
2 No. 2 with the exception perhaps of unspecified
3 lymphomas. If I could get some clarification on
4 unspecified lymphomas?

5 DR. HIRSCHFELD: We were trying to come up
6 with kind of a hybrid schema, so this meant
7 lymphomas which weren't mentioned previously.

8 DR. PRZEPIORKA: No. 3. Are there
9 pediatric lymphomas that have an adult counterpart
10 that is not commonly classified as an adult
11 lymphoma?

12 DR. MURPHY: Not that I know.

13 DR. PRZEPIORKA: I don't know of any adult
14 diseases that would molecularly match a pediatric
15 lymphoma, so I think that would be no.

16 Any other discussion? Did we answer all
17 of your questions, Dr. Hirschfeld and Dr. Pazdur?

18 DR. HIRSCHFELD: I think so, thank you.

19 DR. PRZEPIORKA: Dr. Arceci.

20 **Summary Comments**

21 **Robert J. Arceci, M.D., Ph.D.**

22 DR. ARCECI: I have been doing this sort
23 of as we have been going.

24 [Slide.]

25 Just to give you a feeling for how

1 sometimes you don't think what you think is real,
2 may not be real. Don't take this next slide as an
3 anti-evolutionary slide, but I think it brings up a
4 point, that sometimes what we see is not what we
5 actually get, so forget the first two frames here.

6 [Slide.]

7 This is an old cartoon, but this is the
8 turtle walking in. He walks in and an alligator
9 walks out, this guy says, "Evolution is a fact, so
10 you know it is true," and then, of course, the
11 alligator spits out the turtle, so maybe it wasn't
12 quite--what you see is not what is behind the
13 scenes, and keep that in mind as we go through this
14 stuff.

15 [Slide.]

16 So, these are some of the notes I took
17 down. Hematologic malignancies in terms of
18 Pediatric Rule, commonalities leading to the
19 invocation of this Pediatric Rule. Sorry about the
20 George Bush spelling there, I didn't have time to
21 spell it correctly.

22 Defining usage. I think we all agreed
23 that defining the usage of this Pediatric Rule
24 could be used when you had common target
25 expression, that is, markers. We didn't talk about

1 tumor antigens, but I think we are going to have to
2 discuss it in terms of vaccine development in the
3 future, so I think just the expression of a shared
4 antigen is worthwhile talking about.

5 Common functional targets, that is, Sharon
6 said chimeric proteins that are functionally
7 related to the maintenance of the malignant
8 phenotype.

9 We didn't talk about shared host factors
10 very extensively, but I think it is something that
11 we might consider in terms of, let's say, a host
12 has a specific enzyme defect that would make them
13 more predisposed to efficacy of a drug or
14 metabolism of a drug, so it is something that we
15 maybe think about.

16 Then, I think, as Charlie would say,
17 demonstrated activity in adults with the, quote
18 "same" cancer. We will have to define that.

19 [Slide.]

20 Reasons for exclusivity. Unique tumor
21 biology may be infant AML, JMML, possibly CLL.
22 There are examples we all talked about, and I
23 didn't want to enumerate all those, but I think
24 that you are going to find some that, if there is
25 an adult indication, it is just not going to work,

1 and you may find some in pediatrics, like JMML, we
2 may find a drug there that works that is not going
3 to have relevance to it, AML.

4 Distinctive patient clinical
5 characteristics. Kids with Down's syndrome, kids
6 with inherited predisposition, the elderly. Maybe
7 if a drug is developed in the elderly, maybe it is
8 going to be unique to that group. Infants is
9 another possibility. So, there are going to be
10 reasons why, I think, they can be excluded.

11 Yes, Sharon.

12 DR. MURPHY: Just semantics, but since we
13 are at an FDA hearing, don't you want to change the
14 terminology and say "reasons for waivers" instead
15 of "reasons for exclusivity?"

16 DR. ARCECI: Waivers would be fine.

17 DR. MURPHY: Because exclusivity refers to
18 the freedom from generic competition.

19 DR. ARCECI: Okay.

20 DR. MURPHY: But I think you are talking
21 about these things being where you would issue
22 waivers, right?

23 DR. ARCECI: Yes. Waivers is cool.

24 Any others? Waivers, basically, I think
25 this is what we were talking about.

1 [Slide.]

2 There are some caveats, which I thought
3 were pretty interesting. One thing I think that
4 David brought up particularly, which I would
5 totally agree with biologically is that expression
6 does not always translate to function, so if you
7 express a translocation, it doesn't really mean
8 that it is going to be a relevant target and do you
9 have to prove that the protein is present or that
10 it is relevant.

11 I think that if your drug is designed to
12 inhibit a function, you have got to prove that a
13 protein is being made, and that may not always be
14 the case in all pediatric or adult tumors.

15 There may be cross-tumor commonalities,
16 and Steven brought this up, and I think it is a
17 fascinating idea, that is, if there is like a track
18 in lung cancer, and a track in neuroblastoma, or
19 other brain tumors, there are going to be some
20 lesions, c-kit mutations and gastronomas, AML,
21 there may be some things in solid tumors that we
22 should be broad-minded about in terms of targeting,
23 in terms of pediatric trials, and that should be, I
24 would say, sufficient to say you should do it in
25 pediatrics.

1 Host factors, we have talked about a
2 little bit. There are going to be unique
3 characteristics in pediatrics that you just going
4 to not be able to use it in certain groups of
5 patients.

6 What I would say here is this group here
7 is what Dr. Beckwith would always talk about, moral
8 equivalency, and that is--and I think, Charlie, you
9 brought this up, and Don--if it looks the same,
10 behaves sort of the same, call it the same. So,
11 all those AMLs, all those AOLs that you don't have
12 a specific translocation for, but if it smells
13 right, it probably is right, and should we be
14 treating those patients similarly and also not
15 giving a waiver under those circumstances.

16 I think that is not a bad way to do it -
17 until we can split out more effectively, why not
18 lump them. This is what Beckwith used to always
19 talk about in terms of if you can't make up your
20 mind about a tumor specimen, if it looks
21 aggressive, and it looks like this, it probably is
22 a bad tumor. So, whether it has a certain marker
23 or not is irrelevant.

24 The issue of danger of waiting for a
25 drug's approval before starting studies, I think

1 that this is an important issue in that the ability
2 to start early is going to be really important for
3 pediatric trial development, and we are going to
4 miss out on good studies if we don't do that, like
5 vitamin R that Charlie talked about.

6 [Slide.]

7 So, some issues in terms of the ethics
8 that were brought up. When should pediatric
9 studies with new agents be initiated? I don't
10 think we have an absolute answer on this at this
11 point.

12 When is the right time to do simultaneous
13 development of a new agent in pediatric and in
14 medical oncology? I think it can go either way,
15 but I think that we are going to grapple with this
16 question a little bit more in terms of dose finding
17 and when we should be able to start. What kind of
18 information do we need as pediatric oncologists to
19 start a trial? I don't think we have answered
20 that.

21 Endpoints that would satisfy the Pediatric
22 Rule. We touched on this, but would a study in
23 pediatrics, looking at a surrogate marker, be
24 sufficient to say that a company, for instance, had
25 satisfied the Pediatric Rule, or should it be an

1 efficacy study, or an activity study, and we really
2 didn't answer that question, although we sort of
3 brushed by it a little bit. I think it is
4 important because it really matters.

5 I suspect that a surrogate trial, you can
6 prove proof of principle much more easily and in
7 fewer patients than it would take for an activity
8 or clinical trial, so there is a price tag that is
9 associated with that, as well, but what are the
10 endpoints that we want.

11 My gut feeling would be that if we are
12 going to use a new drug in kids, we should have
13 some potential benefit to justify its use.

14 Down here, it goes along with these three
15 things. McIntyre, the ethicist up in Boston, talks
16 about whose justice and what rationality. So,
17 whose sort of value system are we going to use when
18 we ask kids to participate in these new agent
19 trials? I think we have to be very careful. It
20 should obviously be from their perspective in the
21 end, and not necessarily our or the company's or
22 CTEP's or anybody else's perspective.

23 So, I think this ties into this right
24 here, and is very important stuff that Susan
25 brought up.

1 [Slide.]

2 Then, a couple of last issues. How will
3 priorities be established? I really didn't hear a
4 very clear demonstration of this. I mean we have
5 COG, we have CTEP, a bunch of Cooperative Groups in
6 adults, medical oncology, but is unclear if we have
7 five new agents to test in the subtype of AML,
8 which ones are going to be done, and maybe that
9 should go through strategy groups, through the
10 Cooperative Groups, but maybe not always. I think
11 that is up for discussion right now.

12 Who and which group should be involved?
13 This is something that Susan has asked extensively
14 about, and so who should be sitting at the table to
15 make these decisions.

16 The other issue is how should studies be
17 defined, do they all have to have clinical benefit,
18 and I touched on this just a little while ago.

19 [Slide.]

20 Now, how should new agents be
21 co-developed? Should we be doing an MRC model in
22 certain instances, that is, we sit down, Charlie,
23 and we write a trial on AML together, and the
24 pediatric oncologists do it in their centers, and
25 the adult oncologists do it in their centers, and

1 then we share the data, or should we, in fact, do
2 separate trials in pediatrics and in adults, and I
3 think, Frank, in terms of some of the Phase I work,
4 you have to in order to know what you are dosing
5 and what you are doing, and then just do your
6 separate trials, and then be obligated to sit down
7 and share that data afterwards.

8 So, I don't think we have a clear idea how
9 this should be done, but I think keeping it open is
10 going to be important.

11 How will constructive competitive be
12 enhanced by this? I think one of the things I saw
13 that I feared a little bit in this is that there is
14 now a mechanism of COG with industry, and I am sort
15 of totally committed to COG, too, but I think we
16 have to think about this. Joe Simone would kill us
17 if we didn't talk about it.

18 If you have COG and CTEP deciding on how
19 all new drugs are going to be developed in the U.S.
20 or North America, I think we are doing ourselves
21 and kids a disservice, and I think we want to
22 enhance a little bit more competition, whether that
23 is through consortia or whatever.

24 This should be a very dynamic and
25 competitive environment to do that, and we really

1 didn't touch on that, but I think it impacts on
2 drug companies tremendously in terms of how they
3 approach people, who they approach, who is on the
4 short list, who is the long list, which
5 institutions can get the job done, and I don't
6 think we have decided on that, and I don't think by
7 making a list and having it all go through one
8 group is necessarily the only way to do it.

9 Lastly, we didn't touch on this, but who
10 should be supporting this? The Pediatric Rule
11 applies to industry in a way, but we are talking
12 about diseases that are very rare in applying these
13 drugs.

14 We want those new drugs, but it is
15 assuming that all these new drugs are coming from
16 pharmaceutical companies in a sense, and that may
17 not necessarily be true. I would only argue, and I
18 not necessarily a Democrat, I am far to the left of
19 that, but I think that government may think about
20 planning or anticipating a way to support such
21 pediatric clinical trials without necessarily
22 asking pharmaceutical companies to do that. That
23 may be another mechanism by which to develop these
24 things.

25 [Slide.]

1 Two last slides. In terms of how we do
2 this across subtypes, so a marker like ras or BCL-2
3 that is common amongst all subtypes, I think in
4 this sense, we would just lump and test a trial,
5 and then decide on which ones respond and which
6 ones didn't. That is one model to develop these
7 kinds of trials.

8 Another model is the targeted trial, and
9 this is just a de-acetylation, a hidac inhibitor
10 and demethylator, so if you had a trial designated
11 to respond or to work on core binding factor or
12 leukemias, then, could you hook up with the
13 international community, and I am no sure how the
14 drug companies would look upon that, or the adult
15 groups and target 8;21 and inverted 16 AML, and do
16 your trial in that group solely, and I think we
17 would have to hook up with larger groups in order
18 to effectively do that or else we are not going to
19 have enough patients necessarily to see a
20 difference. You could do that in the
21 post-remission or, in fact, upfront.

22 So, a couple different models to develop
23 those trials, I think are worth continuing to think
24 about. They were brought up throughout the
25 discussion today.

1 [Slide.]

2 Those were just some summary thoughts on
3 this whole thing, and we may actually finish early,
4 it depends on your discussion.

5 DR. PRZEPIORKA: I think the overall
6 message here is that there is quite a laundry list
7 of diseases in adults with counterparts in children
8 for which you could invoke the Pediatric Rule, but
9 the pediatric oncologists would like to also raise
10 your awareness about whether or not there is truly
11 a need to do so, and hope that they could some
12 input into deciding whether or not there is truly a
13 need to do so on individual diseases.

14 Does anyone else have other comments or
15 questions? That was an excellent, excellent
16 summary.

17 DR. REYNOLDS: I think one point that
18 Steve Hirschfeld made earlier, that I would just
19 like to remind everyone of, is that what we have
20 seen also is that there is a paucity of laboratory
21 models for which to prioritize the drugs, and I
22 think that we should see some commitment from all
23 of us towards trying to get such models, because
24 they will allow us to see whether or not there is a
25 response that can be then predictive of what is

1 going to happen in the clinic, and certainly if
2 they had models for that, as Steve suggested, would
3 take a lot of this discussion and make it very
4 simple, because if there was a response on that
5 model, then, you would clearly want to study that
6 drug.

7 DR. HIRSCHFELD: Or perhaps maybe we might
8 believe negatives a little more strongly, and
9 particularly if there were multiple models in,
10 let's say, two out of three of the preclinical
11 models or three out of three in some matrix could
12 give you that type of information.

13 DR. REYNOLDS: Exactly. The negative data
14 might even be more valuable in terms of trying to
15 guide people in terms of applying waivers.

16 DR. PRZEPIORKA: Dr. Weiner.

17 DR. WEINER: I am sorry, I need to run
18 out, and wanted to thank you for this absolutely
19 wonderful summary. Besides the ethical issues, I
20 think the other thing that presses on us is family
21 community, in general, is the need for
22 transparency, which I understand is quite a current
23 term these days according to William Safire, the
24 need for transparency about the prioritization
25 decision-making process. It has got to be open,

1 and it has got to include all of the relevant
2 parties, and it has to have a level playing field,
3 as Dr. Pazdur said.

4 So, thank you.

5 DR. PRZEPIORKA: Dr. Arceci.

6 DR. ARCECI: Pat, I think the one
7 exception to the preclinical models is probably
8 going to be in immunological or vaccine development
9 trials. I may be wrong on this, but it seems like
10 the ability to generate vaccines in preclinical
11 models is probably easier than in humans.

12 That doesn't mean that an approach can't
13 be tried, but it may be one area where a response
14 in an animal may be very unpredictable, I am not
15 sure yet. I hope it is going to be right, but it
16 seems like it is harder in humans.

17 DR. REYNOLDS: I agree with you. I just
18 think that what we need to do is to make a
19 concerted effort to try and develop at least some
20 models, and I don't see why that can't be done and
21 done jointly between NIH, FDA, and industry to try
22 and find some of these models. Even if we do it in
23 a few diseases or one disease, at least we will
24 have a starting point, and even if we only do it
25 for cytotoxics, it would be a starting point.

1 DR. PRZĘPIORKA: Dr. Hirschfeld.

2 DR. HIRSCHFELD: I want to begin by
3 thanking Dr. Arceci for his very eloquent
4 summation, and I wanted to comment that the advice
5 that we got today, and will continue to solicit and
6 continue to receive, should be viewed as, in
7 essence, triggers, and not necessarily absolutes,
8 and what you have helped us is to refine our
9 examination in making determinations when
10 particular disease categories come about, and it
11 doesn't mean that every time such a disease comes
12 about, that automatically, the Pediatric Rule will
13 be invoked, but what it does do is give us a
14 framework to begin to look, and we hope to have a
15 continuing dialogue, so that when disease
16 indications are presented, that we not only have an
17 opportunity to ask the question should the
18 Pediatric Rule be triggered, but we would have some
19 basis for saying yes, we have discussed this
20 publicly, there is scientific evidence to support
21 it, and we would now, in each case, make a
22 determination, and in every case, the sponsor
23 always has the option of applying for a waiver and
24 stating why there should not be.

25 I feel comfortable that between all these

1 checks and balances, that the system should not be
2 become overburdened with the need to establish
3 priorities and that there would arise a
4 circumstance where children with cancer would be
5 viewed as a commodity for further commercialization
6 of a product, but rather that what we would be
7 doing is using the tools at hand to act as
8 catalysts to obtain what we hope would be credible
9 data in areas where these studies are needed.

10 DR. PRZEPIORKA: Other comments or
11 questions?

12 Hearing none, I will call the meeting
13 adjourned.

14 DR. HIRSCHFELD: Thank you, everyone.

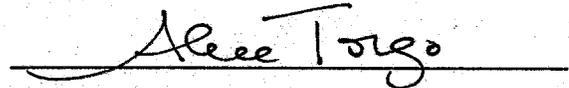
15 DR. PRZEPIORKA: Thank you.

16 [Whereupon, at 3:30 p.m., the meeting
17 adjourned.]

18 - - -

CERTIFICATE

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