

1 which potentially could be used for adult cancer and
2 pediatric cancer alike, does the Pediatric Rule apply to
3 that classification of drugs?

4 DR. HIRSCHFIELD: Dr. Cohn, stay tuned for this
5 afternoon. That is going to be their topic of discussion.

6 DR. CHESNEY: Thank you, Dr. Hirschfield. Dr.
7 Weiner, any concluding comments? Questions?

8 DR. WEINER: Yes, just two comments to response to
9 what Dr. Murphy had asked and also just by way of summary
10 from our perspective, and this is a remark that I made
11 actually in the meeting in February that Dr. Finklestein
12 referred to which is that from our perspective time is
13 really the issue. In implementing FDAMA and the Rule, time
14 is really the question. How long does it actually take to
15 Phase I and Phase II trials in kids, and what is the meaning
16 of that in terms of "incentivizing" the pharmaceutical
17 companies to do this in pediatrics? Will it be worth it?
18 From our perspective, anything that really impedes the
19 progress and the efficiency of the systems involved in
20 evaluating agents and getting new information that is going
21 to be useful for treatment or kids is a bad idea. That is
22 all we have got.

23 The second point I really wanted to address had to
24 do with flexibility. I think, you know, the conversation
25 today has yielded a lot of interesting suggestions about how

1 greater flexibility might be brought to bear with respect to
2 FDAMA and with respect to the implementation of the
3 Pediatric Rule, both formal in terms of the redesign of
4 FDAMA specific provisions for cancer perhaps and, in
5 addition, an informal mechanism such as that which was
6 suggested by Dr. Spielberg and by others, picking up on the
7 notion that, yes, there are informal contacts in industry
8 and personal contacts that, hopefully, will be of benefit
9 but there are also opportunities to bring FDA to the table,
10 as happened in February, so that we can come up with more
11 creative solutions to getting new agents, evaluating new
12 agents, as well as understanding agents that are already
13 approved and already in use in treatment for kids so that we
14 can have sufficient information about those as well.

15 DR. CHESNEY: Thank you for your very thoughtful
16 comments, and I understand there is Valium outside for our
17 FDA colleagues who I think have stood up extremely well to
18 the challenges presented this morning.

19 I would like to reiterate what Dr. Finklestein
20 said, that I really believe this is a "we/we" situation and
21 not a "we/they" and, please, be back by 10:55 and we will
22 attempt to address the question that the FDA specifically
23 gave us. Thank you.

24 [Brief recess]

25

Open Public Hearing

1 DR. CHESNEY: We are past the time for the open
2 public hearing and nobody has signed up but if there is
3 anybody here today that would like to make a comment at the
4 microphone, this would be a good time to do so. Yes?

5 DR. REAMAN: I would just like to make a comment
6 because, as Dr. Finklestein referred to earlier, I was at
7 this meeting in February where there was a great deal of
8 discussion, and certainly the end result of that meeting was
9 that this is a "we/we" situation and we are working together
10 very collaboratively.

11 Subsequent to that, in review of the guidance that
12 was put forth from the FDA there were some concerns as
13 related to flexibility to some of the interpretation, but I
14 must say from my perspective now, being responsible for
15 developmental therapeutics and sharing that responsibility
16 in the Children's Oncology Group, I see absolutely nothing
17 about the guidance which would limit the early access to new
18 agents for children with cancer, and I would really applaud
19 the FDA in everything that they have done to interpret and
20 to remove any obstacles from the Pediatric Rule and FDAMA in
21 ensuring this. Thank you.

22 DR. CHESNEY: Thank you, Dr. Reaman. Any other
23 comments? If not, we need then to go on to the question to
24 the committee, and I wondered if Dr. Hirschfield, Dr. Pazdur
25 or Dr. Murphy would like to read it or interpret it for us,

1 or do we take it as written?

2 DR. HIRSCHFIELD: I think you could take it as
3 written. I could just read it out loud for those who may
4 not have a copy of the question: Special characteristics of
5 pediatric oncology necessitated a more general drug
6 development plan to qualify for the FDAMA pediatric
7 exclusivity incentive. These characteristics are rarity of
8 the diseases, life-threatening natural history of the
9 diseases, biological differences between adult and pediatric
10 tumors, the existence of established cooperative groups, and
11 research protocols as the standard of care. Are there other
12 areas of pediatrics that have similar characteristics that
13 may benefit from a similar approach?

14 **Discussion**

15 DR. CHESNEY: Thank you. Comments from the
16 committee? Yes?

17 DR. PRZEPIORKA: The information that we have been
18 given so far yesterday and today indicates that extension of
19 exclusivity is for drugs and biologics, and I was wondering
20 if this is also true for devices, such as catheters or
21 transdermal delivery systems, or diagnostics for pediatric
22 diseases.

23 DR. MURPHY: The rule includes biologics. Now, if
24 you look at the list that we did publish under the FDAMA
25 requirement, it did include some biologics because we did

1 not look at whether something had a patent or exclusivity,
2 and because biologics normally don't have patents -- that is
3 why exclusivity is not usually including those. So, I am
4 just trying to recognize that there is a little bit of
5 confusion about the fact that we did have some biologics on
6 that list. We were trying to look at products that we
7 thought would have a public health benefit potentially if
8 they were labeled so they were on the list. But, again, as
9 Dr. Pazdur said, you have to have something to attach it to
10 for exclusivity to work. So, that is a problem in that most
11 biologics are not approved where they have that patent
12 mechanism. So. Devices -- no. It does not apply to that
13 either.

14 DR. CHESNEY: Other conditions which might qualify
15 as pediatric oncology has? Dr. Fink?

16 DR. FINK: Well, the two groups that I deal with,
17 cystic fibrosis, although there is a strong national
18 organization there, and the other would be the neuromuscular
19 disorders and, again, there is a strong voluntary health
20 agency that has somewhat taken leadership in those two
21 diseases, but they are similar in that they are life-
22 threatening; they are orphan diseases; and there are care
23 networks through the CF centers and the NMDA centers.

24 DR. CHESNEY: Dr. Luban?

25 DR. LUBAN: I would like to add to that group

1 sickle cell disease. Now, while it might not be life-
2 threatening it certainly is quite morbid and there is,
3 through the sickle cell centers sponsored by NHLBI, a
4 growing clinical trials network.

5 DR. CHESNEY: Maybe I could add one group. I
6 don't think we have any pediatric nephrologists in the room,
7 but having lived with one for 30-plus years --

8 [Laughter]

9 -- who has devoted his career to trying to bring
10 rare pediatric diseases to the attention of Congress, and
11 their needs, I would just like to say that there are many
12 renal diseases that also fall into the same category as Dr.
13 Fink just mentioned. They are relatively rare. They have
14 very strong support groups, and I can't elaborate on them
15 but maybe somebody else in the room can but there is a very
16 elaborate nephrotic syndrome network of investigators that
17 would be similar to some of the pediatric oncology groups.
18 Yes, Dr. Luban?

19 DR. LUBAN: Perhaps Dr. Hudak or Ward could
20 comment on the use of the neonatal networks for some
21 clinical trials, particularly in prematures.

22 DR. HUDAK: Sure, the neonatal network is an NIH
23 sponsored group of study centers for which there is
24 competitive application by sites. It is headed up under NIH
25 CD. I think it has been in existence now for 15 years, and

1 the network I think is a good example of how cooperation
2 between NIH and academic centers can produce some meaningful
3 and important results, and it also illustrates, frankly,
4 some of the perils of doing large, multi-center trials where
5 there is a significant lag phase in terms of an idea gets
6 developed and when it gets implemented, and what happens in
7 the interim in the clinical centers. But, this has led to
8 some important information and clarification of therapies in
9 neonatology, and that is a little bit different model than
10 the orphan type diseases because we are never at a dearth of
11 neonates, and it does target some of the important
12 morbidities that we see in premature babies.

13 DR. WARD: I think the other area that is actively
14 involved in multicenter trials is that of the pediatric
15 pharmacology research units. Dr. Kauffman wanted to comment
16 about it, but that has allowed also multicenter trials to
17 proceed in areas of very important aspects of pediatric
18 therapeutics, and to proceed fairly efficiently.

19 DR. CHESNEY: Yes, Dr. Balis?

20 DR. BALIS: The other disease I want to raise is
21 neurofibromatosis, which is a disease that shares a lot in
22 common with cancer and which many of the new agents that we
23 are developing that are molecularly targeted may have
24 application, but at this point there really is no other
25 standard therapy, other than surgery.

1 DR. CHESNEY: Several other categories that have
2 occurred to me are the immune deficiency diseases; chronic
3 granulomatous disease, very small numbers of patients,
4 inevitably fatal, and I don't know about their support group
5 but certainly SCIDs and some of the other better defined
6 genetic immunodeficiency diseases have very elaborate
7 support groups and networks. Then, the whole area of
8 genetic and metabolic diseases, again, cystinosis falls in
9 that category but probably other people here can think of
10 many more of those. Dr. Danford?

11 DR. DANFORD: I wish I could say that pediatric
12 cardiology and heart disease had things in common with the
13 research protocols and networks available in oncology but,
14 unfortunately, I can't. There are scattered examples of
15 multicenter trials but, by no stretch of the imagination,
16 can we say the standard of care equals Phase III trials even
17 in cardiology conditions that are treated with medicines
18 rather than surgeries.

19 The one place where we could say that there might
20 be that kind of a situation would be in devices, and there
21 the interventional cardiologists do have a well-developed
22 nationwide network. Unfortunately, we just heard that FDAMA
23 and the Pediatric Rule don't apply in those situations.

24 DR. CHESNEY: Dr. Luban?

25 DR. LUBAN: I would like to propose not a group

1 but, rather, a disease phenomenon that crosses groups, that
2 is very, very common and requires a potential application of
3 the rule, and that is in thrombosis, childhood thrombosis --
4 very, very common; unfortunately, poorly treated. At this
5 point, no organized clinical trials, although there have
6 been some moves through the hemophilia treatment centers to
7 incorporate thrombosis trials in those groups. And, with
8 the advent of all of the new low molecular weight heparins,
9 it is potentially an important avenue to explore.

10 DR. CHESNEY: Dr. Fink, I wonder if you could
11 elaborate or tell us a little bit more about the cystic
12 fibrosis situation, which I thought was very analogous to
13 the oncology example.

14 DR. FINK: Well, there are 125 centers that are
15 partially funded by the National CF Foundation that
16 participate in collaborative Phase I, Phase II and Phase III
17 trials, and recently the National Foundation has even gone a
18 step further and developed eight therapeutic development
19 network centers that take care of the Phase I and Phase II
20 trials and to use the entire network for the Phase III
21 trials, so that there is even a gradation, and centering
22 Phase I and Phase II trials in larger academic centers that
23 have a large population and heavy research support has led
24 to more efficient production of Phase I and Phase II trials,
25 and then the Phase III trials obviously, because of patient

1 needs, are spread to the wider network. That has been a
2 combined effort that really has both federal and private
3 funding.

4 DR. CHESNEY: Dr. Luban, could you tell us more
5 about the sickle cell networks?

6 DR. LUBAN: The National Hearth, Blood and Lung
7 Institute has for years funded sickle cell centers which are
8 a combination of both basic science as well as clinical
9 research. For many years the clinical research was very
10 single-institution directed, and it has just been within the
11 last three or four years that there has been more of an
12 attempt to bring those centers together and have them do
13 cooperative clinical investigations and the initiation now
14 of hydroxyurea trials.

15 My understanding from the Branch is that they
16 would like to do more and more clinical trials and, of
17 course, the infrastructure is all paid for already by NIH,
18 with nurse practitioners, data monitors, in a similar way
19 although clearly in a much lower scaled way than the cancer
20 cooperative groups. Certainly, also from a biological
21 perspective, lots of animal models, SCID mouse particularly,
22 as well as pharmacologic manipulation so that as drugs can
23 be developed, and are being developed, there should be a
24 mechanism to do some translational clinical trials.

25 DR. CHESNEY: Yes, Dr. O'Fallon?

1 DR. O'FALLON: I believe there is an AIDS
2 cooperative group for children.

3 DR. CHESNEY: Very active network of AIDS clinical
4 treatment units, of which we have one at St. Jude, very
5 actively involved in sharing data and comparing notes. Yes,
6 Dr. Fink?

7 DR. FINK: Yes, one of the things that occurred to
8 me yesterday when we were talking about psychoactive drugs
9 is that almost all of the diseases and groups we are talking
10 about share the issues of how do you cope at a family level
11 with chronic disease? How do you administer chronic
12 medications, and what do you do with the adolescent with a
13 chronic disease? And, yet, none of the groups probably have
14 the psychiatric expertise or maybe the number of patients to
15 take on that issue, and there clearly is a need across
16 pediatrics to try and understand family and individual
17 coping and growing up with a chronic medical disability.

18 DR. CHESNEY: Thank you. I think we heard about
19 autism yesterday which also very much falls into this
20 category of relatively rare disease with a bad need for new
21 drugs, new approaches. Dr. Ward?

22 DR. WARD: I would like to just provide something
23 of an overview. I think we have just heard of multiple
24 areas in pediatric medicine and pediatric problems that need
25 additional therapeutic research. I think FDAMA can work,

1 and is working in many of these. And, from the February
2 meeting, the FDA proposed mechanism by which trials at Phase
3 I and Phase II level could qualify for exclusivity -- we
4 heard it in its application to oncology drugs, but there are
5 probably many other areas of therapeutics, from cystic
6 fibrosis to cystinosis to other inborn errors of metabolism,
7 that may benefit from that process.

8 When it comes time for renewal, I have concerns
9 about trying to create carve-outs for specific clinical
10 areas, especially if we have a process that can serve all
11 areas of pediatrics effectively, because if one area is
12 carved out and identified as unique many other areas will
13 feel they are also unique, and the potential effect could be
14 an unwinding of congressional support for renewal. And, I
15 think we have to be very cautious in how we proceed over the
16 next 18 months as this comes up for a great deal of debate
17 and discussion.

18 DR. CHESNEY: Thank you. Any other comments?
19 Suggestions for other diseases which the FDA has asked for?
20 I guess, not having been at the February meeting but having
21 worked with our pediatric subcommittee for sometime, I would
22 also like to emphasize what Dr. Ward just said so
23 articulately. I think many of us in the room have disabled
24 children or children with a limited life span, including
25 myself, and I think we would all like a carve-out, if you

1 will, but I think that it is important that we try in every
2 possible way to support FDAMA, and I am very impressed at
3 what the Oncology Group has done at the FDA -- Dr. Pazdur's
4 presentation today -- to work with FDAMA, and I just would
5 like to reiterate what Dr. Ward said, that we should all try
6 at every level to support what has been a historic
7 contribution to pediatric care.

8 DR. MURPHY: I guess I want to second or third
9 that because I think when you go to Congress you never know
10 what you are going to come out with at the end, folks. So,
11 we have something that is working. We are working on ways
12 to make it work better where we have identified problems.
13 If you tinker with it too much, you don't know that you are
14 going to get it at all, first of all, secondly, you don't
15 know what you are going to end up with.

16 It is like a new child having certain infirmities
17 and we want to trade it in for another child, I would say
18 let us work with this child and support developing this
19 child, if you will, because it truly is a program in its
20 infancy. Think about what the potential would be for moving
21 all these various fields forward, if we could ever get to
22 the point where we actually had products that are already
23 out there that aren't labeled and get them studied, plus
24 then move these developmental fields forward in all these
25 areas of science -- we have an opportunity here, and I would

1 caution some restraint as we go forward and, instead of
2 trying to fix every single problem use the tools we have
3 been given and work with them and work to have FDAMA renewed
4 very much in the format that it is -- not that FDA doesn't
5 have its problems either with it, but we really believe that
6 we are just now discovering how to work with this
7 opportunity in the most positive way. Thank you.

8 DR. CHESNEY: Dr. Spielberg:

9 DR. SPIELBERG: I would fourth that. With the
10 perspective of having been in pediatric pharmacology for 25
11 years, this really is historic. I think most of us who have
12 been in the field for a long period of time never would have
13 imagined that we would be in the position where we are today
14 where a lot of the past issues are no longer issues; where
15 drugs are being actively studied; where large numbers of
16 compounds which had been orphan for many, many years are now
17 being actively studied.

18 The renewal of the legislation really is crucial I
19 think not only to the issue of getting drugs studied, but
20 really also has tremendous impact on the overall activities
21 within pediatric departments around the country. It has
22 stimulated a great deal of translational research.

23 If I can be critical of departments of pediatrics
24 because I was in them for many years, even when I was junior
25 faculty I was told there were two things you could do,

1 molecular biological or patient care, and that was it, and
2 molecular biological was too difficult for clinicians and,
3 after all, the molecular biologists didn't understand
4 anything about patients so they should stay away.

5 What this has done is revitalize the whole issue
6 of translational research. The old model which I was taught
7 in the '60s in medical school of bench to bedside really
8 does have validity, of getting science to the patients who
9 need it, and this initiative has really reawakened that in a
10 remarkable way. It is truly critical for renewal not only
11 for pharmacologic interventions but really for clinical
12 investigation in pediatrics in general.

13 And, there are certain things that have been done
14 around the sites independent of the FDAMA effort, and I
15 think that is another lesson that we can take. If there are
16 specific issues, we can go outside the legislation to try to
17 fix certain things. One example is that we have been
18 working on legislation to increase the number of pediatric
19 pharmacology trainees, you know, Ralph and I -- Bob is the
20 only one who doesn't share our hairdo -- but we all are
21 getting old and we recognize that so many years have gone by
22 without pediatric departments focusing on the need for
23 translational research that the next generation of
24 translational researchers isn't there.

25 But that legislation, including some clever things

1 that Sen. Dodd's and DeWine's office came up with of debt
2 forgiveness of those who go into pediatric investigation and
3 stay in that field, along with additional support for the
4 PPRU network to actually support the training slots that are
5 needed, is really one aspect of things that we can work on
6 independent of FDAMA, but even that initiative is truly
7 dependent on FDAMA renewal otherwise we are going to be
8 training people who won't have jobs in the long run. One of
9 the neatest things about trying to train young people is
10 that they will have jobs, otherwise why spend all those
11 years? And, FDAMA provides routes for pediatricians to be
12 involved in government, to be at FDA, to be at NIH. It
13 provides routes for them to go into industry because
14 industry will be working on pediatric projects, and it will
15 obviously provide routes for their careers in academia so
16 that the studies can be carried out.

17 So, you know, if you look at that piece of
18 legislation for trainees and then you look at FDAMA you say,
19 "aha, the two work together and they really do complement
20 each other." Similarly, I think as time goes by, I think
21 Dianne is right, I mean we have had -- what? -- a year and a
22 half experience with this, barely two; ten drugs getting
23 labeled in the previous ten years for kids and eleven drugs
24 getting labeled in the last year. I mean, that is a ten-
25 fold increase in the rate of activity. And, obviously, from

1 all the compounds that are now being studied, all those
2 things will lead into labels. We have made mistakes and we
3 have realized knowledge gaps. Those knowledge gaps then can
4 be turned into support for NIH funds to study those disease
5 processes so that we can get outcome variables that we can
6 study so that we can, in fact, get drugs properly labeled
7 for kids. It all kind of beings to work together. But
8 critical to the whole effort really is getting FDAMA renewed
9 and keeping the process going.

10 DR. CHESNEY: If I could just make one more
11 comment, my husband, for those of you who don't know, is the
12 chairman of our department but if I had a dollar for every
13 time he has come back from a meeting at the NIH or Congress
14 and said, "I can't stand these internists; they forget that
15 children aren't just little adults and that we absolutely
16 need to focus on pediatric issues." And, I think there have
17 been many positive outcomes of his work and many others, the
18 PPRUs is just an incredible idea. Maybe, Ralph, you can
19 tell me sometime whose idea it was, but these centers that
20 are just devoted to studying drugs in children are just
21 revolutionary. And, I think in so many ways FDAMA
22 represents this major new movement in support of children
23 that I would just add again to Dr. Spielberg's always
24 articulate comments that it is really critical that we try
25 to work within the system or we will be back where we were

1 when internists ran the show -- apologies to any internists
2 in the room! Any other comments? Ralph?

3 DR. KAUFFMAN: I would just add briefly to Steve's
4 comments, and that is we need to understand that renewal of
5 FDAMA is not automatic. There is very powerful opposition
6 out there that will be doing everything possible to try to
7 see that FDAMA is not renewed, and will be lobbying whoever
8 is in Congress next session very aggressively to try to keep
9 this legislation from being renewed. So, it isn't going to
10 be automatic, and all of us are going to have to engage in a
11 concerted effort, those who have the welfare of children at
12 heart, to make sure that this gets done because it certainly
13 is not a sure thing.

14 DR. CHESNEY: Thank you. Dr. Ettinger?

15 MS. ETTINGER: I just feel, from the unique
16 perspective of being at the bedside as a nurse, I can
17 reiterate what Susan had said. It is really important that
18 we put concrete measures from bench to bedside because it is
19 our parents and it is the families who actually drive this
20 including parent support groups in all of these, they are
21 the ones who actually bring it forth and I think it is most
22 important that we continue that.

23 DR. CHESNEY: Dr. Murphy, the last word.

24 DR. MURPHY: I just want to thank you for your
25 thoughts and the fact that, as we move forward in each of

1 these areas, we will be bringing different issues to this
2 committee, again usually supplemented with the
3 subspecialists, as you saw yesterday with neuropharm., and
4 actually they have been one of the more active participants
5 in this last year and a half in trying to help us to develop
6 priority setting in how we move forward in this area. And,
7 we will, as always, listen to what you have said as far as
8 some of the areas that we may need to look at in our future
9 written requests as we try to move the science and the
10 information that is available. Because -- it a very good
11 point to end -- what are we trying to do? People say why is
12 the label so important? Because that is FDA's way of
13 providing the science and the information. Now, we are
14 hoping to develop other mechanisms and being able to
15 transmit the information to the public in other ways besides
16 just the label, but for right now the label is our main say
17 of communicating to both the professional and, through some
18 of our package inserts and med. guides, to the patients and
19 the families. And, that is the goal. The goal is that you
20 will have the right information, meaning you will know how
21 you are dosing the child. The mother and father have the
22 expectation that when their child receives that medicine it
23 will have been studied and we will know that it will work,
24 and we will know how to advise them as to how the adverse
25 effects are. So, we are expanding this spectrum of the

1 preclinical all the way to not just the bedside in the
2 hospital but the bedside at home in the middle of the night
3 when you should be able to expect something as simple and
4 common as your anti-pruritic to have the right dose. So,
5 thank you all very much.

6 DR. CHESNEY: I want to thank all of our speakers
7 today. I want to thank Dr. Smith, Dr. Weiner, Dr. Pazdur,
8 everybody who made contributions and comments this morning.
9 I think this has been a very, very informative session for
10 those of us who are not oncologists.

11 This meeting will reconvene at one o'clock.
12 Yesterday lunch was in the Plaza Cafe and there was room
13 reserved for the FDA; we are not sure if that is true today.
14 I think our executive secretary has an announcement.

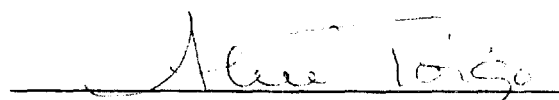
15 DR. TEMPLETON-SOMERS: I just want to clarify this
16 afternoon's meeting because I think there might be some
17 confusion. The pediatric subcommittee of oncology will
18 convene at one o'clock in the Chesapeake Suites to talk
19 about the extrapolation issue, and the pediatric
20 subcommittee of the anti-infective drugs stays in this room
21 and you will be meeting also at one o'clock.

22 DR. CHESNEY: Thank you very much.

23 [Whereupon, at 11:34 a.m., the proceedings were
24 recessed]

C E R T I F I C A T E

I, **ALICE TOIGO**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

A handwritten signature in cursive script, reading "Alice Toigo", is written over a horizontal line.**ALICE TOIGO**

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