

1 see differences between the two formulations, and that's
2 proportional with any other adverse event that is dose-
3 related.

4 Secondly, I want to talk for one second on the
5 design of a trial that would have to look at retreatment.
6 Currently you would expect about 20 percent of the patients
7 to have a retreatment, and that's similar to the
8 information that's in the literature and similar to the
9 information we obtained within the trial. So,
10 consequently, in order to have enough patients to evaluate
11 properly on retreatment, you would need a very large trial
12 design in order to address all of the safety issues on the
13 retreatment, and it would take an extensive period of time
14 to have that type of trial.

15 Thank you.

16 DR. ROSENBERG: Just back to that pregnancy. 3
17 per 1,000 is more than get lung cancer from smoking
18 cigarettes, just so we have it in perspective.

19 DR. BERGFELD: Thank you.

20 Dr. Branch?

21 DR. BRANCH: Given the point that you made, I
22 agree with that. I'm not sure that there is a lot of merit
23 in going down on the dose-response curve unless you've got
24 fairly clear evidence that the adverse event profile also
25 improves. You're clearly close to a peak of your acute

1 response rate. You've got 95 or some very, very high
2 proportion of acute response rate. Clearly there's room to
3 go down there, but if that doesn't meet the criteria you
4 need for sustained benefit, then it seems to me that the
5 key endpoint measure is still your long-term recurrence
6 rate.

7 DR. BERGFELD: Dr. King, will you make that
8 statement publicly?

9 DR. KING: I guess listening to all this, I
10 have something simple. I agree with going down on the
11 dose-response curve doesn't add much, so I agree with Dr.
12 Branch for today that the only thing to look at is adverse
13 events. If there is any suggestion. I don't know how to
14 do that. That was originally in my proposal for the
15 registry. So, I don't want to beat that dog anymore, but
16 adverse events is the only thing you can go after.

17 DR. BERGFELD: Any other discussion? Because
18 I'm going to propose the question.

19 (No response.)

20 DR. BERGFELD: I'm going to say, given the data
21 presented, does the committee feel further dose-ranging
22 studies are needed for isotretinoin? I'm going to call the
23 question as yes. I'll call the question as those in favor
24 of a yes answer, please indicate by raising your hand.
25 That would suggest that other studies need to be done. All

1 | those in favor?

2 | (A show of hands.)

3 | DR. BERGFELD: 5.

4 | Those opposed?

5 | (A show of hands.)

6 | DR. BERGFELD: The vote is 5 and 10.

7 | Any abstaining?

8 | (No response.)

9 | DR. BERGFELD: The answer is no, and so we need
10 | not to discuss anything else. The discussion regarding
11 | possible further studies regarding adverse events have all
12 | been recorded and can be reflected on by the FDA.

13 | Moving then to question 2, does the committee
14 | believe that there may be possible consequences associated
15 | with the simultaneous marketing of Accutane and the new
16 | formulation for both prescribers and patients?

17 | Any discussion here? Dr. Greene, Dr.
18 | Greenhill, and Dr. Lammer.

19 | DR. GREENE: One thing that's not clear to me
20 | is, is the sponsor proposing that these two formulations be
21 | available on the market in perpetuity, or are you going to
22 | change over from one to the other? That's not clear to me.

23 | DR. ELLISON: Absolutely in the beginning they
24 | must both be on the market. You certainly can't expect
25 | people to switch from one to the other.

1 After that, we were interested in what you
2 thought about this, as we're interested in your ideas about
3 this as I think FDA is, what this is going to look like in
4 practice, what you see the risks are, and so on.

5 So, the way this usually goes is we need to see
6 how it looks in that first year of conversion. We intend
7 to be very active in conversion. We're going to be out
8 there with double the frequency of contact because we're
9 rolling out the targeted pregnancy prevention office
10 system, and I'm not sure what else after our discussions
11 yesterday. So, assuming this drug is approved, we will be
12 doing a lot of conversion. So, the question will be how
13 much needs to remain out there totally on the market or
14 compassionate use and so on. So, we're not entirely sure.
15 Your discussion of this will be very helpful to us.

16 DR. GREENE: Well, if I could ask a follow-up
17 question then before you leave the podium. What would be
18 the advantage to maintaining the old formulation as opposed
19 to the new? Why would you want to keep the old one?

20 DR. ELLISON: What we've heard -- and these
21 have been anecdotal -- is that some people want to keep it.
22 Some people around the table are agreeing with that, and
23 there's that reason and that's a meaningful reason I
24 suppose.

25 The other thing is certain patients or certain

1 physicians feel very comfortable with this. It's not a
2 medical reason.

3 I think very often in the early days,
4 particularly physicians who have an office system like the
5 dermatologists here who take this very seriously really
6 want to see that in their hands and their clinic they are
7 getting the effect that they anticipate getting. So,
8 there's always a transit period.

9 That's really it. Normally you would probably,
10 in the course of time, remove the old formulation if there
11 was complete conversion.

12 DR. GREENE: Well, just one more follow-up. It
13 seems to me that the only issue really remaining on the
14 table is that you've got two different outcome measures.
15 One is acute resolution of symptoms that you've studied
16 with the new formulation, and the other is acute and also
17 durable remission that has been studied with the old
18 formulation. Once you have data indicating a durable
19 remission with the new formulation, I'm hard pressed to see
20 the advantage to keeping the old.

21 DR. ELLISON: That would be correct. The
22 problem will be is that it's the one-year relapse-free
23 period that I think for Dr. Rosenberg and others who have
24 been in practice and really understand the value of a
25 permanent approach to severe nodular acne. You'd really

1 have to study people for at least a year. That's, as Jack
2 pointed out, a very long and very arduous study.

3 You could, if one was doing the progressive
4 cohort program that Dr. Mills suggested earlier for
5 psychiatric disease, maybe obtain more data from that kind
6 of situation and that might be a possibility. But the
7 classical clinical trial design would take a very long
8 time. So, it's really going to have to be, I think, one of
9 those situations.

10 Normally speaking, if you can remove the trade
11 formulation, you'd rather do it. It depends if the
12 practitioners really are going to be okay with that.
13 Sometimes you can reserve it for compassionate use only and
14 not really market it to pharmacies, and if people have a
15 special need for it, you can supply it. So, that's really
16 the situation.

17 There is no necessarily rational -- that you
18 can study and provide data for -- reason to keep the old
19 formulation on the market except for the natural transition
20 that people have.

21 DR. GREENE: Well, one year is not that long a
22 study. Certainly there's no cancer therapy that's studied
23 for only one year or less than one year.

24 DR. ELLISON: It's a question of accumulating
25 cases and trying to see a difference because if you were to

1 | compare the formulations to see a difference in relapse
2 | rate, you'd need a very large sample size. So, it took 14
3 | months to recruit the 600 patients. We are known as one of
4 | the faster development organizations in the industry, and
5 | it took us 14 months to do this. So, that's what I mean
6 | not about length of treatment in the trial, but length of
7 | recruitment and that kind of thing. It takes a very long
8 | time.

9 | DR. BERGFELD: You are looking at a three-year
10 | outcome then. Your recruitment, the study, and then
11 | interpretation.

12 | DR. ELLISON: Essentially that's right.

13 | DR. BERGFELD: Dr. Greenhill.

14 | DR. GREENHILL: Just a simple question. Is the
15 | cost of a once-a-day use with NF comparable with twice-a-
16 | day use of Accutane? That's going to have some effect on
17 | prescribing and consumer acceptance.

18 | DR. BERGFELD: Can you address the cost issue,
19 | Dr. Ellison?

20 | DR. ELLISON: We don't know what the price will
21 | be right now. We don't have an approval.

22 | But there is one answer to that, and I think
23 | it's a very important question. About 90-something percent
24 | of prescriptions are reimbursed: 1.4 percent by Medicare
25 | and the rest are from managed care organizations and third-

1 party payers. So, at this point cost is not a barrier to
2 treatment. Certainly we don't anticipate price, in this
3 particular case, compromising that situation.

4 DR. BERGFELD: Dr. Lammer?

5 DR. LAMMER: I work at a hospital where 60
6 percent of the patients are on Medical. Cost is an issue
7 every single day for almost all the patients there.

8 But my comment really here is to reiterate what
9 Dr. O'Connell said earlier that I think if there is a new
10 formulation that comes out, the brand name should be very,
11 very similar to build on the educational activities that
12 have already gone on to make the public and women aware of
13 their need to avoid pregnancy while using the drug. So, I
14 want to just agree with and emphasize that recommendation
15 that was made earlier.

16 DR. BERGFELD: Thank you.

17 Dr. Abel?

18 DR. ABEL: A point of information. What is the
19 situation with regard to generics? Will we have to be
20 concerned that there will be different formulations out
21 there when the patent runs out and we'll have to deal with
22 two different kinds of isotretinoin anyway?

23 DR. BERGFELD: Dr. Bull, Dr. Wilkin, someone,
24 FDA? Dr. Woodcock?

25 DR. WOODCOCK: Any generic drug that would be

1 | approved has to have the same rate and extent absorption to
2 | the reference listed drug. They have to be identical in
3 | their Cmax and area under the curve. The formulations
4 | don't have to be exactly the same for a generic drug. They
5 | can have very minor differences.

6 | DR. BERGFELD: But their efficacy and safety
7 | profiles and adverse event profiles have to be somewhat
8 | comparable, don't they?

9 | DR. WOODCOCK: Are not tested. That's the
10 | difference with a generic. That's why part of this
11 | discussion is interesting because we make an assumption
12 | when a generic drug is approved that if the blood levels
13 | are identical of the active ingredient and the shape of the
14 | curve, the Cmax and the area under the curve, the
15 | absorption, then the effect of the drug, as sort of a basic
16 | biological principle, is going to be the same.

17 | DR. BERGFELD: Could I ask another question
18 | that follows that? The activities that we concurred on
19 | yesterday regarding mandating some educational activity in
20 | a registry and a pregnancy test, would that not apply to
21 | the generics?

22 | DR. WOODCOCK: Absolutely. We have faced this
23 | already with generic drugs where the innovator has had
24 | various voluntary restrictions on them or other programs
25 | associated with them, and we have successfully maintained

1 that any generic copies would have to have an equivalent
2 program. It may not be identical, but it would have to
3 have the equivalent effect because that is intrinsic to the
4 safety and effectiveness of the product.

5 DR. BERGFELD: Thank you.

6 Dr. Epps and then Dr. Miller.

7 DR. EPPS: My only suggestion would be for the
8 company to get on the formularies of the HMOs, insurance
9 companies as quickly as possible. Lately we've been
10 hassled more and more about getting approval for Accutane.
11 We have to fax notes. We have to talk to somebody on the
12 phone to get approval. Sometimes it's denied, and for a
13 patient who really needs it, it's very expensive, as you
14 know. It can easily be over \$1,000 by the time you deal
15 with the tests and the medication, and if they need another
16 course, then it's very expensive. We're starting to get
17 more and more denials. Certainly if it's going to be once
18 a day, it could cost a little bit less. We know you want
19 to recoup your investment, but we are having problems
20 lately getting approval for it.

21 DR. ELLISON: Point taken.

22 I just want to comment to Dr. Lammer. When I
23 said 1.4 scripts were covered, that doesn't mean that
24 Medicare doesn't cover it. It means that of all the
25 prescriptions written, 1.4 percent were paid for by

1 Medicare. So, it's not that it's not covered. It's that's
2 the population that's getting it.

3 As to your point, yes, that's obviously part of
4 the process, so we will be doing that. I take your point.
5 I also take your point about the additional paperwork for
6 prior authorization, and maybe there's something we can do
7 with the databases and so on that can maybe kill two birds
8 -- or what did you say, Dr. King? Put everything in a
9 boat?

10 DR. KING: Yes, load all of your changes in one
11 boat and float them all there because actually at
12 registration, you could actually get the approval and the
13 whole thing at one time. I still say you can't sell the
14 product if you can't get the dermatologist to write it, and
15 he won't write it or she won't write if it's not easy.

16 DR. BERGFELD: Dr. Miller and then Dr.
17 Anderson.

18 DR. MILLER: This is a question for the FDA.
19 Given the restrictions for this drug, what is the
20 anticipated activity with generics?

21 DR. WOODCOCK: Generic competition, of course,
22 is encouraged once the drug goes off patent and when it's
23 at a point where it does not have exclusivity protections.
24 We can't, of course, talk about whether there are any folks
25 in the pipeline or whatever, but generally it depends on

1 | the sales of the drug and how profitable it would be, if
2 | it's intended to have generic copies. Certainly I would
3 | imagine that restrictions on the product would be factored
4 | in to the price equation for any generics.

5 | DR. BERGFELD: Thank you.

6 | Dr. Jennifer Anderson?

7 | DR. JENNIFER ANDERSON: I just had a question.
8 | If the sponsor were to withdraw Accutane before the patent
9 | ran out, would it be possible for generics to enter the
10 | field, or would that be precluded?

11 | DR. WOODCOCK: You can't use a drug as a
12 | reference listed drug if it's been removed for reasons of
13 | safety or other problems. If it's simply been removed for
14 | other reasons, it still could exist as a reference listed
15 | drug, which is the standard to which the generic is
16 | compared.

17 | DR. BERGFELD: Thank you.

18 | Any other discussion? We have 15 minutes.

19 | (No response.)

20 | DR. BERGFELD: I'd like to call this question
21 | because it has a second part if the vote is yes. Again,
22 | does the committee believe that there may be possible
23 | consequences associated with the simultaneous marketing of
24 | Accutane and the new formulation for both prescribers and
25 | patients?

1 The first vote will be for yes. All of those
2 in favor of a yes response, please indicate by raising your
3 hand.

4 (A show of hands.)

5 DR. BERGFELD: 14.

6 Negative, please raise your hand?

7 (A show of hands.)

8 DR. BERGFELD: 1.

9 Abstaining?

10 (No response.)

11 DR. BERGFELD: None.

12 If the answer is yes, then we must continue.

13 If yes, please comment on the appropriate strategies to
14 alleviate them.

15 Yes, Dr. Holmboe?

16 DR. HOLMBOE: I think one area is going to need
17 to be again at the level of the pharmacist when they pick
18 up the drug. It may be an area where a medication guide
19 could be specific to the type of formulation with a warning
20 that this is a once-a-day versus a twice-a-day drug. You
21 can actually put them in front of it.

22 DR. BERGFELD: So, you're recommending a
23 recommendation of a medication guide for this.

24 Dr. King and then Dr. Greene?

25 DR. KING: I think it's going to be a whole lot

1 | like Classic Coke whether it sells or doesn't sell.

2 | (laughter.)

3 | DR. KING: I think it's going to be actually a
4 | period of three years in which Hoffmann-LaRoche and the FDA
5 | are going to have a period in which they're going to phase
6 | it in and phase it out based on the economics, et cetera.

7 | That's why I proposed the original study. If
8 | you're going to float a boat, you might as well put all of
9 | it there. So, if you're going to take about a three-year
10 | study to show equivalence, you might as well say we're
11 | going to change in three years. That's always subject to
12 | if it doesn't sell. You can't sell it if nobody is going
13 | to buy it.

14 | So, I think that would be a prime window to
15 | make the phase-out and it would leave Hoffmann-LaRoche and
16 | FDA to deal with issues of whether or not the generics are
17 | going to be, A, major competitors or, B, if they're going
18 | to come up with the same kind of safety profile.

19 | DR. BERGFELD: Dr. Greene?

20 | DR. GREENE: I would just like to echo what Ed
21 | Lammer said a couple of minutes ago, and that is I don't
22 | want all the effort that has gone into the education,
23 | marketing, et cetera of Accutane to date with respect to
24 | its potential problems to be lost on the new formulation.
25 | I don't want somehow there to be some confusion that this

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