

1 suppose the recommendation was that a woman test -- would  
2 it be 14 days or something like that? They would be glad  
3 to do that. A urine test is not intrusive. What's so  
4 great about once a month? If 14 days would really do some  
5 possible good, why not mandate it?

6 DR. BERGFELD: Any comments? Dr. Greene?

7 DR. GREENE: Yes. I guess the comment I have  
8 is what do you mean by mandate? We can recommend.

9 DR. ROSENBERG: Urge.

10 DR. GREENE: Thank you.

11 DR. BERGFELD: Any other comments? Dr.  
12 Winokur?

13 DR. WINOKUR: I was just going to go back and  
14 second Dr. King's endorsement of plan 3, which seems like,  
15 I agree, the best balance for the goals right now. It does  
16 include the education and the assurance of a negative  
17 pregnancy test before releasing the next prescription  
18 without going too far down the road with the more heavy-  
19 duty emphasis on other methods of contraception that may be  
20 beyond where many people have stated being willing to focus  
21 on at this point. Again, I think that, linked with the  
22 really outstanding education program that Roche is  
23 developing, sounds like a very valuable step forward at  
24 this point.

25 DR. BERGFELD: So, I gather that we've had a

1 motion and we've had a second. Roche would like to  
2 comment? The motion was to accept design 3, as I  
3 understand.

4 DR. MITCHELL: I appreciate your giving me the  
5 opportunity. Just two points.

6 One is that there has been a lot of discussion  
7 about the STEPS program. We have been involved both with  
8 the design and the monitoring, the observation, and I might  
9 add interventions currently with the STEPS program. Jay  
10 Kaminski described some of the aspects of it. But I think  
11 that there have been some numbers tossed around, and I  
12 would like to provide some clarification.

13 Among the people enrolled, men and women, in  
14 the STEPS program, there have been approximately 760 women  
15 of childbearing potential, among whom to date there have  
16 been 0 pregnancies. That 0 has an upper confidence bound  
17 of somewhere approximating what we've observed for  
18 Accutane. It's not to suggest that it will be the same,  
19 but I think it is too early -- and this is a personal  
20 opinion -- to declare victory for STEPS. I think that it  
21 was the most dramatic and the most well thought out and the  
22 most comprehensive program ever developed, and it is  
23 currently being evaluated. As Jay pointed out, it's being  
24 revised. It required, as would some of the proposals,  
25 development of entirely new systems that don't currently

1 | exist in this country. As a group that has had the  
2 | headache of trying to monitor what's going on with STEPS, I  
3 | can tell you that it is not an easy solution. The data  
4 | simply tell us that, although very promising, it is not yet  
5 | in my view the solution for every drug.

6 |           Further, among the 761 women, most of them are  
7 | older. Most of them are very sick. A large majority have  
8 | cancer. Most of those are multiple myeloma. These are not  
9 | young, healthy women who are highly at risk for pregnancy  
10 | to start with, so that the population differences need to  
11 | be taken into account.

12 |           As a separate point -- and one of the concerns  
13 | we've had in hearing the discussions and, as my friend and  
14 | colleague, Dr. Mills, would support, we epidemiologists  
15 | always want the biggest denominator we can get and usually  
16 | we want it all. The problem is, how do you interpret the  
17 | numerators from the denominator that is now mandated?  
18 | We've been able to get response rates in the survey of 80  
19 | to 98 percent, we believe the results that we're getting  
20 | from this population of women who have elected to  
21 | participate.

22 |           What I'm not clear about is if the ultimate  
23 | test of the value of a new approach is the pregnancy rate,  
24 | how do we measure that pregnancy rate and how do we have  
25 | confidence that what we've measured is accurate? I don't

1 | have an answer for that. I just raise the question. Thank  
2 | you.

3 | DR. BERGFELD: Thank you very much.

4 | Dr. Moore?

5 | DR. MOORE: I just want to add a comment. I  
6 | found it very difficult -- maybe it's a good thing that I'm  
7 | not a voting member -- to go through all the options and  
8 | decide which one I thought would help meet those goals.  
9 | Some of it, I think, from going through a lot of the things  
10 | on the Thalomid program.

11 | But it seems to me that we're dealing with a  
12 | very potent teratogen, and it's unique in that for most of  
13 | the women, if I understand the data correctly, they're  
14 | using this drug for 5 months. I think it was 25 percent or  
15 | something like that would have a second course of this.  
16 | So, we have a very defined period of time for these women  
17 | to help them prevent pregnancy. I believe, as someone said  
18 | here, that that would be every woman's goal, to not have a  
19 | pregnancy during this time.

20 | The dividing line that I saw between the  
21 | additional things that were proposed by Roche and what the  
22 | FDA had given us, several options, was the mandatory nature  
23 | of it. For me, when I look at those different options, the  
24 | first one, that all patients be registered, that implies to  
25 | me that the physician is doing something. I felt like that

1 the other goals sort of skipped over or maybe didn't  
2 explicitly say that the physician is the one who is  
3 prescribing these drugs and has a responsibility. To me  
4 there should be some mandatory obligation for the  
5 physician, and I think that's a good dividing line.

6 Are we talking about a program, as Roche has  
7 said, that's all voluntary whether the physician tells the  
8 woman anything or not, or are we talking about some sort of  
9 mandatory components where women have to be told, have to  
10 be educated, have to be given the tools that they need?  
11 The details of working that out, I think as Dr. Mitchell is  
12 saying, are going to very complicated, and I'm not quite  
13 sure that voting on 1, 2, or 3, you won't find something  
14 that makes that sort of impossible in this situation. But  
15 saying yes, something absolutely has to be done, that's not  
16 optional that some tools have to given to these women and  
17 we need to help them. I think that's a good dividing line  
18 more than 1, 2, 3, 4, or 5.

19 DR. BERGFELD: You are responding in a normal  
20 manner as all committee members have to face these  
21 questions. Over the years of chairing such a group,  
22 everyone has this similar frustration. But I think that  
23 the FDA could respond. Dr. Woodcock, maybe you'd like to  
24 respond.

25 DR. WOODCOCK: Our question that we're asking

1 | here is what elements best balance the possible benefits of  
2 | preventing pregnancy against the burdens. That's really  
3 | what we're talking about here, and we're asking for broad  
4 | strokes. We're not asking for details. We recognize the  
5 | problems with implementation. We recognize that we have  
6 | not really clearly elucidated for you the burdens, which is  
7 | a problem.

8 |           For example, in restricted distribution of  
9 | pharmacies, we certainly do not envision the pharmacists  
10 | grilling the women in the pharmacy line about her pregnancy  
11 | status. We were thinking about a link back to a database  
12 | that shows that shows that the woman has, in fact, had her  
13 | appointment and had the pregnancy status verified. So,  
14 | privacy would be maintained.

15 |           So, I think you're going to have to tell us in  
16 | broad strokes what you think the elements are that are  
17 | important to you and not get into the details for that  
18 | reason.

19 |           DR. BERGFELD: Dr. Moore, does that satisfy  
20 | you? As well as it can I guess.

21 |           Dr. Greenhill?

22 |           DR. GREENHILL: I just had a couple of  
23 | questions. I'm a nonvoting member, but I just wanted to  
24 | make some comments about the proceedings.

25 |           I'm very impressed with Hoffmann-LaRoche's

1 overall program to provide materials to the patient and to  
2 the physician. I do have a couple of comments about the  
3 materials, and I think it's an essential part of any of the  
4 programs we're voting on.

5           The booklet for moms, the Step 8 Preventing  
6 Pregnancy, A Guide to Contraception, is very well written  
7 but my impression is that it would be most appreciated by  
8 someone who has completed college. A lot of the  
9 individuals who will be dealing with Accutane are the same  
10 population that the HIV programs have worked long and hard  
11 to reach with immediacy, short, pithy kinds of comments,  
12 very pictorial materials.

13           I think I would encourage Hoffmann-LaRoche to  
14 field test these materials with populations of adolescent  
15 girls and young adult women before they settle on this  
16 particular package. I could not find the 800 number within  
17 the mom's booklet. I did find it in some of the other  
18 materials. So, if these materials are separated, the mom  
19 will not be able to get to the 1-800 number, and that  
20 should be prominently flashed in neon kinds of colors in  
21 the booklet.

22           Even so, in looking at the choices, if I were  
23 a voting member, I might have some difficulties. It looks  
24 like the difference between choice 3 and 4, as best I can  
25 identify it, are reports of contraceptive use. Under pros,

1 | it says contraceptive counseling. That's the new added  
2 | element between design 3 and 4. I thought contraceptive  
3 | counseling was part of all the packages. So, I'm not sure  
4 | how 3 and 4 differ exactly other than maybe there's some  
5 | more attention that contraceptive monitoring has to be done  
6 | with each visit just to remind the mom of the importance.

7 |           If that's the difference between 3 and 4, I  
8 | would go for regular reminders to the mothers about the  
9 | importance of dual contraception and discussions, continued  
10 | discussion, perhaps not necessarily with the physician in  
11 | the office, maybe a nurse clinician who works with the  
12 | physician, but just to monitor that to see how it's going  
13 | because it may turn out that the mom is beginning to do  
14 | something, let's say, that month that would lead her down  
15 | the path to becoming at risk for pregnancy, and if she were  
16 | to discuss it, she would realize what's going on and avert  
17 | a pregnancy.

18 |           DR. ROSENBERG: Don't call her mom.

19 |           DR. GREENHILL: Sorry.

20 |           DR. VEGA: Your last statement about what's the  
21 | purpose of the introduction of the contraception counseling  
22 | is precisely that. It's to more formally address the  
23 | issue, ask the question, and document if they are aware  
24 | that they are following the contraception methods that they  
25 | decided at the beginning of treatment.

1 I want to express a concern I have. I hear a  
2 lot of the details and I think that it's easier to perhaps  
3 conceptually think about these designs, and then later on  
4 we can get into the more specific details because it's  
5 really distracting. For example, the issue that Dr.  
6 Mitchell presented about the lack of a numerator. Well,  
7 the answer to that is that if we are documenting pregnancy  
8 tests, then we're going to know which are those positive  
9 pregnancy tests because they will be potentially entered  
10 into the system. So, that will help us get a numerator.

11 So, I would just encourage you to look at the  
12 big picture and maybe consider the elements and the fine  
13 details could be very distracting.

14 DR. BERGFELD: I'm sorry. I seemed to have  
15 missed the exact statement that you made about the  
16 difference between design 3 and 4. Can you be very  
17 succinct about that difference?

18 DR. VEGA: In design 4, we have just added the  
19 documentation of the use of contraceptive method. It's  
20 required as part of the program. It's going to be  
21 documented, the same as the pregnancy test, that that  
22 questioning has been done and that the physician has  
23 assessed that specific element.

24 DR. GREENHILL: On a repeated basis?

25 DR. VEGA: On a monthly basis.

1 DR. BERGFELD: I'm going to call on everyone  
2 over here.

3 That is not part of the current Roche program?  
4 I'm sorry. It is.

5 MS. LEACH: It is. Yes, monthly pregnancy  
6 testing is part of the program, and to Dr. Miller's point,  
7 there is a flow sheet for the physician, a progress note  
8 that has all of the elements for a monthly visit.

9 DR. BERGFELD: Dr. Ellison and then Dr. Vega.

10 DR. ELLISON: A couple of points of  
11 clarification. I wonder if you understand that in our  
12 program in the documentation is that we are, to some  
13 extent, registering physicians. This is this whole process  
14 of going out and doing this. It's not a mandatory  
15 registry, although it's interesting that we will be  
16 covering all of dermatology with respect to CME. We will  
17 know who doesn't want to have CME but we suspect that's  
18 going to be very small.

19 Secondly, the phone call into the pharmacist  
20 with the confirmation of two negative pregnancy tests at  
21 the beginning of treatment and the phone call in the next  
22 month and the next month offers an opportunity to look at  
23 this, as I said, within standard pharmacy practice.

24 That's the remarks that I wanted to make at  
25 this point.

1 DR. BERGFELD: I'd like to ask you a question  
2 as the chair. You've seen these five designs put up before  
3 you. Where best do you feel that the company fits?

4 DR. ELLISON: A couple of small comments and  
5 then I think overall impression. First of all, to address  
6 Dr. Vega's point, the assumption that you're going to catch  
7 all the pregnancies is based on two things, that all access  
8 is through pharmacy and that they come back to the pharmacy  
9 with that positive pregnancy test.

10 The larger issue I think is how to make this  
11 work. I think the FDA has put up some designs about  
12 databases and so on that have been used in the past, et  
13 cetera. Our major concern is that this functionality of  
14 trying to check if people say they agree to contraception,  
15 if they say they did contraception, that part of it I think  
16 is very important to understand how that's going to work  
17 and the kinds of responses you're going to get to that.  
18 This is where an anxiety about the mandatory nature of  
19 this, a reliance on it, on a formal system for women who  
20 have to avoid pregnancy every day of therapy, and the idea  
21 that it's going to give us data that's of sufficient value  
22 to really know what's going on.

23 Most of my comments were made in my closing  
24 remarks. So, our view is we have been working, since  
25 actually we looked at these options with FDA, internally to

1 | try to look at ways of doing this that would be somewhat  
2 | newer and innovative and wouldn't rely on the  
3 | conditionality of a script which we think is what creates  
4 | the greatest risk.

5 | Thank you.

6 | DR. BERGFELD: Dr. Woodcock.

7 | DR. WOODCOCK: Just to clarify, I think the  
8 | major difference here between what Roche is operating now  
9 | or proposing to operate and the elements of the designs  
10 | that are on these proposals is the fact that there's a  
11 | system in place to make sure and document whether or not  
12 | these things actually happen. It isn't that Roche isn't  
13 | intending for all these things to happen and recommending  
14 | for them to happen in the current environment, in the  
15 | current targeted pregnancy prevention.

16 | This puts a systems approach in place, that  
17 | there is a system that every time these things have to  
18 | happen. That's what we're asking. It does create an  
19 | additional burden on the clinician because they have to do  
20 | it and they have to document. And potentially on the  
21 | pharmacist as well.

22 | DR. BERGFELD: I'm going to go down this side.  
23 | First Dr. Abel, then Dr. Jennifer Anderson, then Dr. Branch  
24 | and Levin. Dr. Abel?

25 | DR. ABEL: A question as to the voting

1 procedure. If we vote on 3, does that mean we can also  
2 bring up 4? Because 4 includes all the elements of 3  
3 except one additional one. I agree with 3, but I think  
4 documenting the different types of contraception is a good  
5 idea. I know there's a motion up to vote on 3.

6 DR. BERGFELD: Essentially we would have to  
7 vote down the motion for 3 and then propose 4 unless the  
8 motion makers change their position.

9 DR. KING: No. I'll just comment that when you  
10 do the education and informed consent, you've already done  
11 that. So, I don't think you can give informed consent.  
12 Our lawyers say that just because you signed a form, you  
13 didn't prove knowledge or understanding. You just proved  
14 you signed the form. So, my view of this is, if you want  
15 to document that the patient is pregnant or not, it gets  
16 intrusive, but as long as you're doing a pregnancy test and  
17 education, I don't have much trouble with 4. I just prefer  
18 3.

19 DR. ABEL: Where are you documenting this? In  
20 the doctor's records or on some checklist form for Roche?

21 DR. KING: In the doctor's record. The reason  
22 we did this is we had a quality assurance for over a year  
23 trying to prove, for example, that every time we had a skin  
24 biopsy that showed a cancer, we called the patient. So, we  
25 said why don't we extend this to Accutane.

1           So, we call the patient every month to document  
2           that they were, in fact, taking it, were not pregnant, et  
3           cetera. It was minimal intrusiveness, but it also let us  
4           know what our dropout rate was to go find those because our  
5           lawyers said that we were at risk for failure to diagnose.  
6           So, I do pay attention to those kinds of things. Zero  
7           tolerance is a zero tolerance.

8           DR. ABEL: I would like to vote against the  
9           restricted distribution to pharmacies. Dr. Miller referred  
10          to some simple way. Couldn't it be just documented in a  
11          prescription that the pregnancy test was negative and then  
12          that patient take that prescription saying the pregnancy  
13          test was negative to the pharmacist so there doesn't have  
14          to be some sort of database that the pharmacist has to  
15          check into?

16          DR. BERGFELD: That's all possible.

17          DR. ABEL: And one other question I had is what  
18          exactly is meant by registration of physicians? I'm not  
19          sure. Does that mean registering for CME, registering for  
20          prescribing contraceptives? What is the registry?

21          DR. BERGFELD: Dr. Vega.

22          DR. VEGA: The registry of the physicians is  
23          what allows the doctors to access some database to document  
24          the pregnancy status of the woman. So, as a physician, if  
25          I'm registered, I have my, let's say, personal code to

1 | access a database and enter this specific patient's  
2 | information. Otherwise, anybody can access patient  
3 | information and enter into the database.

4 | DR. ABEL: They have that information from the  
5 | laboratory report. The patient goes to the lab.

6 | DR. VEGA: But if we want that information to  
7 | be documented to an outside source.

8 | DR. ABEL: To an outside agency.

9 | DR. VEGA: Exactly. Into a central center or  
10 | database.

11 | DR. BERGFELD: Does that satisfy you, Dr. Abel?  
12 | Okay.

13 | I have two Dr. Andersons. First Dr. Gloria  
14 | Anderson, then Dr. Jennifer Anderson.

15 | DR. GLORIA ANDERSON: I just have some  
16 | questions that might clarify some things in my mind. I  
17 | think I've been hearing today that we're distributing a  
18 | drug that causes some real problems, yet we're not quite  
19 | sure of the people we're distributing it to. And we're not  
20 | even sure of all the physicians who are distributing it.  
21 | We also don't seem to be sure about the educational  
22 | process, that is, how effective it is.

23 | I'm concerned about the whole educational  
24 | process from the standpoint of those persons who are  
25 | probably below that 14 -- I think I saw a median

1 educational level of 14 years at some point this morning.  
2 And that's fine. Even people with 14 years probably don't  
3 do what they're supposed to do. But you've got a whole  
4 group of people who are far below that that probably have  
5 some serious problems.

6 Then there is the whole problem created by the  
7 managed care industry where some physicians at least may  
8 not have time to do what they should do in terms of  
9 education.

10 I guess I'm not hearing the answers. I'm not  
11 offering any suggestions, but I would like to hear some  
12 answers particularly as they relate to the educational  
13 process. The registration of the physicians I thought  
14 would include some kind of tabulation on the dispensing of  
15 the drug, at least the people who are getting it so that we  
16 know who is getting this drug. Then our data perhaps would  
17 become a bit more accurate.

18 I am concerned that we apparently don't have as  
19 much information as we should have on the whole educational  
20 process and how effective it is. That's the real concern  
21 that I have. I'm not sure which one of these plans would  
22 address that issue.

23 DR. BERGFELD: Dr. Vega, could you shortly,  
24 succinctly respond?

25 DR. VEGA: I'm not sure I understand the

1 question.

2 DR. GLORIA ANDERSON: I didn't really ask a  
3 question. I expressed some concerns.

4 DR. VEGA: Well, I think that the educational  
5 module that Roche has developed is outstanding, and I think  
6 that it's implicit that each one of these designs is  
7 carrying that module as part of it.

8 DR. GLORIA ANDERSON: I'm not questioning the  
9 quality of the materials or the quality of the program. I  
10 have a concern, I should say, for the effectiveness of the  
11 program or perhaps the lack of effectiveness because it  
12 requires implementation by a variety of types of people  
13 across the country at various months and times and who have  
14 various interests and all sorts of things. I'm sure  
15 dermatologists would be more interested in doing their job  
16 than perhaps a primary care physician who is maybe closer  
17 to a general practitioner. I'm not questioning the quality  
18 of the materials, and I didn't ask a question either.

19 DR. BERGFELD: I'm not sure we can address all  
20 that in the length that it needs to be addressed.

21 Dr. Vega, could you respond in any way or,  
22 Roche, in any short way?

23 DR. GLORIA ANDERSON: The one question that I  
24 did raise was regarding the registration or certification  
25 of the physicians. You said he or she could tap into a

1 database to get information on the pregnancy status. I  
2 think that's what you said. Is that the only relationship  
3 of the registration to the dispensing of the drug?

4 DR. VEGA: Again, I think that I mentioned that  
5 when the physician registers, it just gives him or her an  
6 access to the data center where the information for the  
7 patients is going to be documented. So, that's the link  
8 between the registration of the physician, just to give him  
9 access to this information, to document the patient  
10 information.

11 About your other concern about the efficacy of  
12 the education --

13 DR. BERGFELD: I don't think we can address all  
14 of the concerns that you have at this particular time.

15 DR. GLORIA ANDERSON: No. I didn't really want  
16 them addressed. I wanted the committee to understand the  
17 difficulty I have in trying to make a decision about how to  
18 respond to this request.

19 DR. BERGFELD: Thank you.

20 I think that I have several people here yet who  
21 want to speak. Dr. Jennifer Anderson.

22 DR. JENNIFER ANDERSON: Yes. I'm confused  
23 because in the way that these different designs were  
24 presented and what you said just now, Dr. Vega, design 1 is  
25 the Roche proposal and then the others build on that. But

1 then Dr. Woodcock said that we would be just voting in  
2 principle, conceptually, without voting for any specific  
3 form of implementation. What is the correct --

4 DR. BERGFELD: Dr. Woodcock?

5 DR. WOODCOCK: The chair can decide exactly how  
6 you want the voting, whether you want to vote separately  
7 for each one of these or as we ask in the question. We're  
8 asking what do you think of these elements, and I was  
9 saying don't get into the exquisite details of how they  
10 will be implemented. We're asking the committee's advice  
11 on is a formal, required linkage between pregnancy testing  
12 and filling a prescription -- do you think that is a  
13 desirable element of a risk management plan for this drug.  
14 That's the kind of high level we're asking for.

15 DR. JENNIFER ANDERSON: And the elements about  
16 education and tracking of pregnancy exposures that were  
17 part of education and informed consent and tracking of  
18 pregnancy exposures that are part of the Roche proposal are  
19 being voted on, whichever design, not specifically as they  
20 were there but just in principle?

21 DR. BERGFELD: Dr. Vega?

22 DR. VEGA: Yes. In principle, because I should  
23 have mentioned that, although we have heard the discussion  
24 under the Roche pregnancy prevention program proposal, all  
25 the elements under the Roche proposal are voluntary. For

1 | example, in the tracking of pregnancy exposures, there are  
2 | some good elements there, and we are carrying that on, but  
3 | once you pass from design 1 to design 2, all these become  
4 | mandatory. So, that's a difference. They are present and  
5 | that's why they have all X's, but the nature of the  
6 | requirement changes once you cross the line between 1 and  
7 | 2.

8 | DR. BERGFELD: Dr. Levin?

9 | MR. LEVIN: It seemed to me that the best way  
10 | to characterize this was the most essential difference was  
11 | moving this from a voluntary system to a mandatory system  
12 | to be inclusive of all women taking this drug and to  
13 | mandate these procedures. And that's a big change. But if  
14 | you were going to characterize it very quickly, wouldn't  
15 | that sort of do it? And then there are some add-ons to  
16 | that, but that the basic move is to say, okay, we're not  
17 | just going to rely on the sponsor to do this on a voluntary  
18 | basis. We're going to mandate that a lot of what the  
19 | sponsor has already done we agree with and we're going to  
20 | mandate this across the board.

21 | Just one other question. I just want to  
22 | understand a little better about what our current  
23 | experience is with the authorized pharmacy only option. We  
24 | have thalidomide where there are authorized pharmacies  
25 | only. Am I correct? And we have Clozaril, clozapine,

1 | where we had authorized pharmacies, but that was a burden  
2 | and we no longer have authorized pharmacies.

3 |           Any comment on what you think the experience  
4 | with thalidomide is? Are we going to get to the same place  
5 | with thalidomide where it's handled in a different way?  
6 | And if that's the case, shouldn't we be thinking along  
7 | those lines?

8 |           DR. BERGFELD: Dr. Vega?

9 |           DR. VEGA: Are you specifically addressing  
10 | design number 5 with the pharmacy distribution  
11 | restrictions?

12 |           MR. LEVIN: Yes.

13 |           DR. VEGA: I don't know what's going to happen  
14 | with thalidomide, so it's very hard for me to tell what's  
15 | going to happen in the future. But so far it's my  
16 | understanding that the pharmacy restriction of the  
17 | distribution at that level hasn't had any adverse results  
18 | other than, I should say, as I mentioned when I was going  
19 | through the cons of that design, it has the potential for  
20 | restricting the access to patients.

21 |           DR. BERGFELD: Thank you.

22 |           Dr. Holmboe?

23 |           DR. HOLMBOE: I just want to make a couple  
24 | points.

25 |           One is with regard to the registration. I

1 | understand the practitioner would simply have to register  
2 | into a database. My concern actually is for that 15  
3 | percent of people who are not dermatologists who may not be  
4 | knowledgeable enough to use this drug. To be perfectly  
5 | frank, I'm a general internist. You will never see me  
6 | prescribe this drug. It's not because I lack the knowledge  
7 | because, after going through these tomes of information for  
8 | 3 weeks, I feel I know a lot about this drug now.

9 |           The problem I see for a lot of these other  
10 | areas outside of dermatology offices is systems within the  
11 | office to do all this stuff that's being suggested. Has  
12 | the FDA thought with regard to restricting the use of this  
13 | drug to only dermatologists instead of simply creating a  
14 | database where people can register?

15 |           DR. WOODCOCK: I believe our approach, as laid  
16 | out here, is actually to ensure that there is a system for  
17 | the people who use this drug that supports the proper use.  
18 | So, that system, in its full-blown element, number 5, would  
19 | basically ensure that the systems were in place and whoever  
20 | decided to prescribe this drug would have to take that  
21 | seriously and have those systems in place because they  
22 | would have to document that they were in place.

23 |           DR. BERGFELD: Thank you.

24 |           Dr. Branch?

25 |           DR. BRANCH: In terms of stepping back a little

1 bit and saying why have this program at all and to what  
2 level should we have it, it seems to me that there's been  
3 excellent evidence that education has been effective, a  
4 very high level of people have been educated. There's been  
5 a tremendous reduction in the number of women who have  
6 actually been pregnant. But the most impressive piece of  
7 data is that there is still a persistent problem.

8 If you use the working approach the Institute  
9 of Medicine has recently suggested in management of adverse  
10 drug reactions, you ask two questions. One is education.  
11 The other one is process, the process of delivery. It  
12 seems to me that in this instance the education has been  
13 played pretty close to a hilt, that it really is time to  
14 change the process.

15 And the key elements that I see coming in here  
16 -- I don't know about plan 1, 2, 3, but I think the key  
17 implementation parts are a uniform set of guidelines which  
18 everyone is expected and has to follow. So, the  
19 registration is a byproduct of trying to create a sense of  
20 uniformity there, and the second is that you're involving  
21 the pharmacy in a decision making process in a support  
22 process, and I think that that is a very sensible use of  
23 health care systems. So, to me it makes imminent logical  
24 sense to take those two pieces as being the core elements  
25 of what's being approved, and how you phrase it and how you

1 get down to the detail is detail.

2 But I think taking advantage of your full  
3 health care team and being able to get a uniformity of how  
4 you process and handle an individual patient and maximize  
5 safety -- the information is known. It really is a process  
6 issue.

7 So, I think that the closest one that I see  
8 within that definition is 3, but I wouldn't really be too  
9 perturbed with 2. I think the other component -- and I  
10 really feel for Roche in this. I think they've done a  
11 superb job in their program they put in. I think number 4  
12 is already handled by the Roche program. I think the  
13 minimum burden that can be added to meet those priorities  
14 would be a workable plan.

15 DR. BERGFELD: Thank you.

16 We have one more individual who wishes to  
17 speak, Dr. Miller, and I would like to know if anyone else  
18 would like to address the question before I call for the  
19 vote. Dr. Miller?

20 DR. MILLER: This is a point of clarification,  
21 and I don't want to belabor it because I had the same  
22 question that Dr. Branch did or the same thoughts about  
23 this. How do you envision the role of the pharmacy  
24 differing among 3, 4, and 5?

25 Because I think that it's absolutely crucial

1 that pharmacists be involved in the educational process,  
2 that they be very much educated about this drug and that  
3 they're very circumspect in the way they handle it and the  
4 way they look at it. My concern is that the lesser designs  
5 might not address that issue the way 4 and 5 might.

6 DR. VEGA: Well, the only design that contains  
7 restricted distribution at the pharmacy level is number 5.  
8 In essence, the pharmacist is going to be doing the same  
9 thing as the pharmacist has been doing in design 3 and  
10 design 4. The addition of a restricted distribution is the  
11 added burden for the pharmacist to document that that  
12 verification is going on, and only those pharmacists with  
13 that certification, if you will, will be authorized to  
14 carry and dispense the drug. Does that answer your  
15 question?

16 DR. BERGFELD: Is there anyone on the panel who  
17 has not spoken to the issue they wish to speak? I see one  
18 person. Dr. Byrne?

19 DR. BYRNE: I actually didn't have any major  
20 comments to make. The only thing I would say is that  
21 anything that would clarify that the process was in place,  
22 i.e., a database or anything that would enable people to be  
23 tracked and enable the verification of negative pregnancy  
24 testing, and obviate the necessity to have unnecessary  
25 pregnancies must be a positive thing.

1 DR. BERGFELD: Thank you.

2 Does anyone else wish to speak at this point?

3 Yes, Dr. Malone?

4 DR. MALONE: I just have a follow-up question  
5 regarding the pharmacy. In step 3 and 4, if you're  
6 requiring pregnancy tests, would the pharmacy be able to  
7 dispense without the pregnancy test, or there would be some  
8 system that prevents that?

9 DR. VEGA: If you look at design 3 and design  
10 4, they both have the pregnancy testing linkage. So, that  
11 pregnancy test results needs to be documented somewhere,  
12 and the pharmacist is going to double check that so that  
13 their intervention is the verification process of that  
14 documentation.

15 DR. BERGFELD: Yes, Dr. Greenhill.

16 DR. GREENHILL: Dr. Vega, if you could clarify  
17 one more time the difference between design 4 and design 3  
18 is the mandatory requirement that the discussion of  
19 contraception occur every month rather than voluntary?

20 DR. VEGA: That's correct.

21 DR. BERGFELD: Yes, Dr. Bull.

22 DR. BULL: Given that there was a vote taken on  
23 the goals, there is a chart that links these design  
24 elements back to the goals. It might just be helpful,  
25 before you take a vote, to take a look at that.

1 DR. BERGFELD: Do you want to walk us through  
2 it?

3 DR. BULL: There has been I think a fair amount  
4 of discussion looking at design 3. Our assessment is that  
5 in design 3 where there's a plus, those are where you  
6 clearly meet those goals. You'll observe that in terms of  
7 the design's ability to avoid pregnancy during therapy,  
8 it's a plus/minus there because the contraceptive linkage  
9 is not as firm, and when you move into designs 4 and 5,  
10 certainly 5 is assessed as probably the more complete  
11 program. But just to make sure that we're closing this  
12 loop in terms of the goals that you've already voted on and  
13 where these designs fit.

14 DR. BERGFELD: Thank you. I think that helps  
15 the committee members to vote.

16 I'm going to now call for the vote. The vote  
17 is to suggest that design 3 be the accepted design for the  
18 FDA's consideration. It has been moved and seconded and  
19 well discussed. I'd like to call for the vote. All those  
20 in favor, please indicate by raising your hand.

21 (A show of hands.)

22 DR. BERGFELD: Opposed?

23 (A show of hands.)

24 DR. BERGFELD: One.

25 Abstaining?

1 (A show of hands.)

2 DR. BERGFELD: Two. Thank you very much.

3 I think then we can move on to question 3 and  
4 some of the discussion that we've just had will, indeed,  
5 apply to question 3. How can the FDA best monitor the  
6 impact of the pregnancy prevention program? They've listed  
7 some possible options and these include: one, registration  
8 of additional parties, and they put in parentheses  
9 "patients or pharmacists." Two, obtaining data on  
10 compliance with the program. Three, utilizing an external  
11 monitoring program to assess pregnancy exposures and  
12 outcomes.

13 Dr. Rosenberg?

14 DR. ROSENBERG: I would yield to their  
15 inventiveness. They're experts at this sort of thing.  
16 We've told them that we were all for it.

17 DR. BERGFELD: Dr. Woodcock or Dr. Vega?

18 DR. VEGA: Since you have selected design  
19 number 3, it already has the linkage. Let's start with the  
20 first one, the registration of additional parties. Design  
21 number 3 includes registration of patients and physicians.  
22 So, that number 1 is taken care of. It's engineered  
23 already into that design.

24 Number 2, obtaining data on compliance with the  
25 program is already part of design 3.

1 | be used in order to monitor pregnancies.

2 |           I have one other issue in terms of another  
3 | program that I think should at least be considered. That  
4 | relates to this issue that 70 percent of women who become  
5 | pregnant on Accutane, in fact, elect a therapeutic  
6 | abortion. Many of those women are clearly being lost in  
7 | terms of the programs that have been set up. I think that  
8 | Planned Parenthood is a program that should be considered  
9 | seriously in terms of this. This is a huge group that  
10 | involves a large number of women throughout this country  
11 | that get inadvertently pregnant and who are not necessarily  
12 | of the educational group that might end up going to Slone.  
13 | I think that this is a group that we should definitely  
14 | consider in terms of trying to involve them in this  
15 | ascertainment.

16 |           DR. BERGFELD: Thank you.

17 |           DR. HOLMBOE: Just one last plea to the FDA and  
18 | to Roche to strongly consider looking at the process that  
19 | occurs in the offices between the patient and physician. I  
20 | think it's important to learn what the best practices are  
21 | in the offices so that information can be disseminated to  
22 | other offices, and that will make I think also your  
23 | monitoring data more valuable.

24 |           DR. BERGFELD: Thank you.

25 |           Dr. Greene?

1 DR. GREENE: Ken, I'm not 100 percent sure what  
2 your point was about Planned Parenthood. Is your point  
3 that that would be another place to ascertain exposures,  
4 similar to OTIS?

5 DR. JONES: That is, yes.

6 DR. BERGFELD: Dr. Rosenberg.

7 DR. ROSENBERG: I just want to harp one last  
8 time on the frequency of pregnancy testing, the 2 weeks,  
9 which has some scientific advantage over the 30 days, which  
10 is the doctor's visit. I think we should be thinking about  
11 what's best for the patient and not what's convenient for  
12 the doctor.

13 I will just take a minute to speak from my own  
14 personal experience. I've had a radical prostatectomy, and  
15 the urologist says you come back every year and we'll do a  
16 PSA test. And I had a discussion with a fellow  
17 prostatectomy, another dermatologist, and he said, well,  
18 that's nuts. He said, I go every 4 months. He said, I  
19 don't see any reason to wait till I go back to see him. I  
20 just pay for it myself, and he said, I heard a talk that  
21 said it's a better idea. I sure go every 4 months.

22 I think girls can go every 2 weeks, if it's  
23 going to help them. I think the fact of seeing a urine  
24 test is about all the counseling a person would need to  
25 remind them of the importance of it and the opportunity to

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