

1 you're correct that we did not do that in the sort of
2 wild-world setting where they are completely on their
3 own.

4 That would have been very hard to follow
5 them as to what they did and that kind of a design
6 might actually be better done post-marketing.

7 But the trial that we did, they were not
8 given appointments to come back. They were not given
9 a lot of specific instructions on what to do, but they
10 were given an eight-week supply of drug and told when
11 you need a new supply come back to the site and they
12 did that on their own in high proportions and got
13 their lipids tested. That's the extent of the data
14 that we have available.

15 CHAIRMAN BRASS: But following up on that,
16 it's my understanding that in most of the studies,
17 even the patients who said my cholesterol is between
18 200 and 240, when they were tested, less than half of
19 them were actually in that range. Is that correct?

20 DR. LAROUCHE: You're asking me about the
21 accuracy of their cholesterol knowledge?

22 CHAIRMAN BRASS: Yes. So when they
23 responded on the self-selection portion of the study,
24 is your cholesterol between 200 and 240, they said
25 yes, then when you measured it, less than half of them

1 were?

2 DR. LAROUCHE: No, it was 56 percent in
3 one trial and 61 in the other trial, of those people
4 who thought they were between 200 and 240. The
5 numbers were much more accurate when they were above
6 240.

7 There were about 88 percent who were
8 correct. We're not expecting people to have totally
9 accurate recall. We are actually expecting them to
10 check their cholesterols before they start that,
11 whether they do that in a doctor's office or in one of
12 the community-based settings, because that's why they
13 would have an incentive to continue treatment.

14 CHAIRMAN BRASS: I thought in study 076,
15 of the 3,500 patients who got their cholesterol tested
16 after being potentially qualified by everybody, 2,800
17 of them were not in the range.

18 DR. LAROUCHE: This is a slide from study
19 76 which is the best data we have for assessing their
20 accuracy.

21 We asked them on the questionnaire what
22 they thought their cholesterol range was, and of those
23 people who felt they knew their range and it was
24 within the OTC range of 200 to 240, 56 percent were
25 correct and 40 percent were incorrect and their values

1 were above the 240 in actuality, though thought it was
2 between.

3 And of those people who were above 240, 88
4 percent of them were correct. And the top figure, the
5 56 percent, is pretty well confirmed by a similar
6 assessment done in the other study.

7 CHAIRMAN BRASS: But when you say plus or
8 minus ten, does that mean you extended the range to
9 190 to 250?

10 DR. LAROUCHE: Right. We said that if
11 they thought their cholesterol was between 200 and
12 240, but it measured within that little broader
13 window, because we figured there was some wiggle room
14 for variability.

15 CHAIRMAN BRASS: Okay. Again, part of
16 this comes back to the selection point.

17 DR. SEGAL: Excuse me, may I just make a
18 comment?

19 CHAIRMAN BRASS: Okay.

20 DR. SEGAL: In 081, the group with over
21 240 milligrams per deciliter cholesterol self-selected
22 incorrectly with regard to cholesterol, about 46
23 percent of the time.

24 CHAIRMAN BRASS: So whether the number is
25 46, 56, to the degree that self-selection of this

1 range is important, to the degree it's important, and
2 I understand it may not be if you're greater than 240,
3 but let's just say to the degree it's important and to
4 the degree the compliance with that label is
5 important, I think the studies demonstrate
6 emphatically that they cannot self-select for the
7 reasons identified.

8 Now whether that nonselection is important
9 or not, you can discuss. But I think clearly the data
10 shows that patients do not self-select by the criteria
11 on that label.

12 We can debate whether those are strict
13 criteria, guidelines, whether there's a risk of being
14 wrong, but I think the issue is that they do not
15 adequately self-select. The issue is whether that
16 matters a great deal or not in it's actual OTC use.

17 Go ahead, I guess I interrupted you.

18 DR. NEILL: Actually, I was going to move
19 on to patient monitoring now because I still haven't
20 heard any data that was collected to evaluate the
21 ability of consumers to evaluate response to
22 treatment.

23 The sponsor has evaluated response to
24 treatment, but the question that I'm being asked to
25 address is whether the consumers have the ability to

1 evaluate response to treatment? And to help me answer
2 that, I feel like I need to know, what is the
3 consumer's understanding of the expected result? How
4 did they measure their lipid profile in vivo, not in
5 the study?

6 You don't need to address that issue again
7 if you don't like, but I don't have any data about how
8 patients, how well or how poorly they present back to
9 my office, or to a pharmacy community-based setting to
10 do this.

11 And even if I understand that they do it
12 100 percent to have their lipids checked, I don't have
13 any data that informs me about their ability to
14 evaluate response to treatment.

15 DR. SLATER: Okay, let me try. There's a
16 lot of questions involved in that. They're given a
17 card, if you looked in the privileged information that
18 you were given, and they're asked on that card at
19 various intervals to fill in what their level is.

20 We did not attempt to study the question
21 that you're asking. We could easily if you wanted.
22 They are encouraged to communicate that information
23 back to their physician.

24 That's, at this point, where we are at in
25 terms of this paradigm. We clearly could work more on

1 the compliance side. As I told you earlier, our
2 primary focus here was at the front end, namely at the
3 self-selection.

4 To get to the issue of cholesterol recall,
5 and I don't know if Dr. Brass, if you're going to
6 there or not. This again, is sort of more of a survey
7 of what people recall. The vision here is if patients
8 --

9 DR. NEILL: I'm going to interrupt briefly
10 because using the card, I want to go back to this
11 paradigm that exists so far. I guess not what I'm
12 asking you is did something like that exist, but
13 rather how well do patients understand it and use and
14 --

15 DR. SLATER: We have to look. We haven't
16 looked.

17 DR. NEILL: Got it.

18 DR. SLATER: The second point regarding
19 recall of cholesterol. You saw the little test kit
20 this morning. I don't wish to endorse any particular
21 brand, and nor did we intend to endorse any particular
22 brand of testing, but the presumption here would be,
23 and you say that you're not aware of how widespread it
24 really is, but the presumption is that were this
25 medicine to become available, were people to avail

1 themselves, they would also have the opportunity to
2 get the tests done right at the moment in case they
3 think they're okay for it, as a double check, as a
4 recent check, as an up-to-date check in addition to
5 being asked to call their physician if they know
6 they've had a recent test in the last year, but they
7 don't remember their number, again they are being
8 encouraged to call and recover that number.

9 So we're not trying to ask people to wing
10 it and I don't want the Committee again to get carried
11 away that we're asking them to rely on memory, because
12 as we all get older I'm not so sure how good that is.

13 DR. SEGAL: I'd like to make a comment to
14 respond to you. The way I understood the trials, the
15 actual use trials, was that there really were no
16 treatment goals conveyed to the consumer. The concept
17 was, if you take lovastatin, your cholesterol might go
18 down, but there was no number for how far down it
19 might go.

20 There was the concept that cholesterol is
21 bad and people who have high cholesterol get sick, but
22 there was no conferring of information to the consumer
23 about what they would need to do with that range of
24 cholesterol in these studies 200 to 240, how long they
25 would need to take this medicine to keep from getting

1 a heart attack or a stroke or perhaps avoid peripheral
2 vascular disease.

3 So, somebody could have taken, with
4 lovastatin, they could have taken 10 milligrams and
5 had a cholesterol of 240 and an LDL of 180 and maybe
6 their cholesterol would have gone down to 220, maybe
7 their LDL could have gone to, pick a number,
8 somewhere, 150, and they would not have understood
9 from the way these trials were defined, that that
10 might not be where they needed to be if they were a
11 smoker or if they had a low HDL.

12 So there really was no treatment goal
13 defined as far as I could discern from these trials.

14 CHAIRMAN BRASS: Dr. Clark.

15 DR. CLARK: Yes. One point of the
16 question, I think I ought to agree with your last two
17 comments in that if the entry points for treatment are
18 pretty clearly defined, but if the entry point is
19 based on a number, then the patients will need to know
20 what they are seeking to achieve in terms of their
21 goal so that when they get a follow-up they know
22 whether or not the medication they are taking has had
23 an effect and what to do about it.

24 The other though, I would ask perhaps for
25 a comment for the role of the physician in this

1 because there is a discordance in terms of what is
2 being recommended to the patients about taking a drug
3 therapy and what is contained in current guidelines
4 for drug therapy that physicians are likely to be
5 following.

6 These recommendations may be fine, but if
7 the physician is following current guidelines that
8 maybe contain, either from NCEP or their managed care
9 group, and a patient goes to them, there's a great
10 likelihood of being told that the patient may not even
11 need drug therapy because current recommendations
12 don't recommend drug therapy for these patients, and
13 I think that potential for confusion needs to be dealt
14 with up front so that the physician and the patient
15 are not getting different messages.

16 CHAIRMAN BRASS: Yes. I'd just like to
17 follow up. We heard that the lovastatin prescription
18 label has been modified to incorporate the primary
19 prevention information from AFCAPS and I think one of
20 the issues, following up what you've said, is
21 acknowledging that physicians can do this better using
22 dose titration, monitoring, and intensive
23 intervention.

24 I think we have to understand that we're
25 on a learning curve for the profession, as you've

1 alluded to. Not that I'm going to be the defender of
2 medical care in the United States, but much of the
3 primary prevention data has only come out in the past
4 couple of years and to see that beginning to impact on
5 prescription utilization in a variety of settings, I
6 think you're just beginning to see the impact on.

7 Just like it took many years for secondary
8 prevention to reach a nonoptimal, but reasonably high
9 level that continues to be developed in special
10 populations.

11 The National Myocardial Infarct Registry
12 continues to show increases in use of statins for
13 secondary prevention and I think the timing of how we
14 look at what the behavior of the medical community is,
15 is a lagging indicator because much of the primary
16 prevention information is relatively new on the scale
17 of our ability to monitor behaviors. You had a
18 comment?

19 DR. TAMBORLANE: I think you slipped it
20 in, I just want to highlight this issue on the
21 labeling about how much information is provided to the
22 consumer and the duration of therapy that's required.
23 That this is in fact lifelong therapy. This is not
24 just take it for Christmas dinner. And I don't
25 remember hearing anything about that information being

1 provided in the label.

2 CHAIRMAN BRASS: Other comments?

3 DR. SEGAL: That information was not in
4 the label.

5 DR. DONALD UDEN: Is it truly lifelong
6 therapy if in fact somebody --

7 DR. HEMWALL: Excuse me, I just wanted to
8 say, we do have the information in our inserts and our
9 packaging and in all the materials. This is a
10 continuous therapy, that one does not take it
11 intermittently.

12 DR. DONALD UDEN: Is it truly lifelong
13 therapy if somebody has a total cholesterol of 220 and
14 falls in that range, and gets the religion of diet and
15 exercise.

16 It then is not necessarily lifelong
17 therapy, and so if they do that, there would have to
18 be a point in time where they take a drug holiday to
19 see what their cholesterol is off of therapy.

20 CHAIRMAN BRASS: Dr. Neill.

21 DR. NEILL: The corollary to that is the
22 patient's age and other competing co-morbidities
23 arise.

24 For example, a diagnosis of cancer or
25 progression of another chronic disease, which sets a

1 horizon shorter than an expected adverse event from
2 cardiovascular disease, it would be much more
3 difficult to show benefit.

4 But that's true for the prescription
5 product and for many of the other chronic conditions
6 that we treat. And it's not really directly related
7 I think to the selection process or this question four
8 that we're talking about. It is very important, but
9 not to question four.

10 CHAIRMAN BRASS: Dr. Katz, would you like
11 a vote on this, or would is that discussion adequate
12 for that point? Okay.

13 The next is a mirror-image discussion,
14 though we managed to get to letter G, related to the
15 safety issues concerning 10 milligrams.

16 Specifically, in the OTC setting, the
17 ability of the consumer to identify adverse reactions,
18 ability of the consumer to monitor hepatic safety,
19 including the need for hepatic transaminases, the need
20 for and ability to identify and avoid interacting
21 drugs, the likelihood of use of lovastatin at higher
22 than recommended doses, the ability of women who are
23 pregnant or are likely to become to appropriately
24 avoid use, the need for the physician or other
25 healthcare professionals in the safe treatment, the

1 capacity of the proposed label to direct consumers in
2 the safe use.

3 Open for discussion. Yes, right Katz.

4 DR. KATZ: We've had more discussion. Can
5 you back to question four and actually get a vote?

6 CHAIRMAN BRASS: You would like a vote on
7 number four? Just on the global question or on each
8 individual piece?

9 DR. KATZ: On the global question.

10 CHAIRMAN BRASS: So let me read number
11 four again for a vote.

12 Assuming as an indication for the use of
13 lovastatin 10 milligrams in the proposed target
14 population could be justified based on an expectation
15 of clinical benefit, has the sponsor adequately
16 demonstrated that consumers can achieve such a
17 clinical benefit in an OTC setting?

18 All who believe that has been
19 demonstrated, please raise your hand and vote yes.

20 All those who feel it has not been
21 demonstrated, please raise your hand and vote no.

22 DR. TITUS: Thirteen noes.

23 CHAIRMAN BRASS: Abstentions?

24 So, 0 yeses, 13 noes.

25 Discussion on the safety issue. Let me

1 begin by just highlighting some things that came up
2 earlier. I think that the issue of avoiding
3 interacting drugs is extremely problematic trying to
4 list individual drugs and perhaps as was suggested by
5 one of my colleagues, the more blanket statement, if
6 you're taking any prescription drug do not use, may be
7 a more effective warning.

8 Let me also say that I am extremely
9 concerned about whenever we are labeling these OTC
10 studies as actual use study, they are in fact still
11 much more intensively monitored than actual consumer
12 use in the real world, in my opinion, ever is.

13 And that I think it's extremely difficult
14 to extrapolate that kind of experience even with the
15 relative numbers that were shown here today to what
16 the patterns of consumer use and understanding will
17 actually be, so that the likelihood of a consumer who
18 is already on a lipid-lowering drug, taking the drug,
19 is unknown.

20 That just because under intensive,
21 relatively intensive monitoring by a physician in the
22 prescription setting, that 10 milligrams has
23 demonstrated an outstanding safety profile as we
24 previously voted on.

25 I do not know how to extrapolate that

1 experience to how consumers will actually use the
2 product over the counter given that we have concerns
3 expressed that there are higher risk situations. We
4 don't know how much higher risk those situations are,
5 but have heard mention of them, and I don't think we
6 have any data or reassurance from the "actual use
7 studies" that have been presented, how many consumers
8 in those high-risk groups will actually be exposed to
9 the statins if permitted to be used over the counter.

10 And finally, I remain with my hypothetical
11 concern that since healthcare providers can do this
12 better, how many patients, and I view this as a safety
13 issue because it's avoiding optimal therapy, how many
14 patients will not seek a healthcare provider because
15 they think they are being adequately treated by an
16 over-the-counter product? And I remain concerned
17 about that as a safety issue. Other comments? Yes.

18 DR. EDWARD KRENZELOK: I don't think that
19 I have the same concerns about safety that you've
20 expressed. Again, as the sponsor has demonstrated,
21 there are 24 million human-years of use and I think we
22 have to look at actual experiential information.

23 Granted, spontaneous reporting is not the
24 best obviously. There is not active surveillance
25 going on. But it seems like there is a more than

1 adequate safety profile for this particular substance
2 and I think this may be one of those situations where
3 we indeed can extrapolate from clinical use and give
4 it a fairly clean bill of health from that standpoint.

5 CHAIRMAN BRASS: So, for example, you
6 would be confident that the likelihood of a patient on
7 erythromycin taking OTC lovastatin is not higher than
8 prescription?

9 DR. EDWARD KRENZELOK: I think I'd feel
10 relatively comfortable with that, and for the most
11 part that occurs across the spectrum of all drugs.

12 I don't think consumers understand what
13 they take and it's clear that they probably don't
14 understand what they take in combination with
15 lovastatin either. And there hasn't been an
16 inordinate number of adverse events.

17 CHAIRMAN BRASS: Yes.

18 DR. ELASHOFF: I have a concern about two
19 of them. One is, it seems to me that those who have
20 cholesterol higher than is specified on the package
21 are fairly likely to take two or three times the dose
22 because obviously if this wasn't quite enough for
23 that, you take more.

24 The other issue that I'm concerned about
25 is in the prescription setting, is it routinely

1 prescribed for women who are pregnant or likely to
2 become so, and if not, then we really don't have any
3 information about safety in that population?

4 CHAIRMAN BRASS: I don't know if sponsor
5 wants to respond to the pregnancy issue. It's clearly
6 not routinely used. There was some safety data
7 presented in the materials distributed based on your
8 experience. I don't know if you want to add anything
9 to that.

10 DR. HEMWALL: Well, typically these drugs
11 are not given to pregnant women because there is no
12 benefit to be had in a women who is pregnant to carry
13 on with that product during that short period of
14 pregnancy.

15 If they have a hypercholesterolemia that
16 requires that sort of treatment, they interrupt the
17 treatment. We don't have that much experience in
18 pregnant women for that reason and like all OTC drugs,
19 this one as well, would be warned against using in
20 pregnant women.

21 CHAIRMAN BRASS: Dr. Johnson.

22 DR. JULIE JOHNSON: If I can just run down
23 this little list?

24 CHAIRMAN BRASS: Feel free.

25 DR. JULIE JOHNSON: The ability to

1 identify adverse reactions, I think most importantly
2 that would be the myalgias or myopathy, and while I
3 don't think they demonstrated that, that's probably
4 because there wasn't much observed. I think that it's
5 reasonable that a patient could identify that,
6 although I'm a little concerned about the placement of
7 that warning in the package insert. It's under the
8 don't use with the following medicines warning, which
9 implies that you could only get that if you're taking
10 these medicines, which I think could make people who
11 aren't taking any of those medicines ignore that
12 warning.

13 So I think that that would need to be a
14 separate warning on the label. But I do think that
15 consumers could identify that. I don't believe there
16 is a need, and I think that was well documented to
17 monitor the hepatic transaminases.

18 The ability to avoid interacting drugs, I
19 agree that it may not be logical to have a specific
20 list since the list is obviously changing. I'm not
21 sure that I agree that it should say if you're on any
22 prescription drug don't take this, but rather if you
23 are taking any prescription drug please consult your
24 doctor or pharmacist to determine whether this is a
25 safe product in you.

1 In terms of the pregnancy issue, I think
2 your data pretty well documented with the information
3 that you have, there doesn't appear to be risk should
4 a pregnant woman be exposed.

5 CHAIRMAN BRASS: If I could just follow up
6 on the myopathy rhabdo issue. Do either sponsor or
7 the agency have, from the spontaneous reporting, the
8 distribution by year, of those reports?

9 And what I'm wondering about, I'm
10 wondering if people have stopped reporting rhabdo and
11 myopathy since it is on the label as an adverse event?

12 Experience with adverse event reporting
13 often is that the reporting decreases over time,
14 particularly for an adverse event that is on the
15 label.

16 And when we talk about the denominator of
17 24 million, or whatever that number was, I'm wondering
18 if that is skewing because people are not reporting
19 the myopathy anymore into the spontaneous reporting
20 database. And I know in our setting we don't for
21 example. And I know we've seen myopathies and we've
22 never reported it.

23 DR. KORN: We have a distribution of
24 overall number of spontaneous reports per year which
25 of course peaked around early 1990s and has gone on

1 since then. We do not have it broken down
2 specifically for myopathy.

3 CHAIRMAN BRASS: So it's quite likely that
4 the myopathy follows a similar pattern, so that the
5 true denominator might be really only the experience
6 in the first few years, not the full 13 years of
7 experience, hypothetically?

8 DR. KORN: Yes, that's true.

9 CHAIRMAN BRASS: Dr. Temple.

10 DR. ROBERT TEMPLE: There's a presumption
11 that that's so. This observation was made by someone
12 named Weber a long time ago and it's called the Weber
13 curve, that reports of any given reaction drop off
14 after about three years.

15 It has to be noted though that at the very
16 same time we've intensely simulated reports, so that
17 whereas we had 20,000 a year a decade or so ago, we
18 now have 300,000, so the net effect of all that is
19 hard to know.

20 For what it's worth, when mibefradil came
21 out, we got seven reports of rhabdomyolysis associated
22 with simvastatin and it in about two months. So
23 people can be provoked to report.

24 CHAIRMAN BRASS: Yes, Dr. Parks.

25 DR. PARKS: Another thing I wanted to add

1 to that with respect to reporting rates, often a
2 labeled event may not be something that clinicians may
3 report because they are under the assumption that this
4 is something that is already known and toxicity is
5 already known, and therefore it does not need to be
6 brought to the attention of the drug company or to the
7 FDA.

8 CHAIRMAN BRASS: Yes.

9 DR. LUKERT: I'm concerned about two other
10 groups of patients. I don't think we have a way of
11 estimating how many people this would affect, but I'm
12 concerned about the patient who's hypercholesterolemic
13 because they are hypothyroid for example.

14 We can't assume that all patients who have
15 a modestly elevated cholesterol just follow the
16 primary category. And I say this because I see a
17 number of laboratory people who have the ability to
18 check their own cholesterol and do and start starving
19 themselves and lo and behold, they're hypothyroid and
20 finally get discovered.

21 The other is the group of "worried well"
22 who are likely to take this drug, even with a normal
23 cholesterol or even perhaps a rather low HDL. The
24 same group of people who take all kinds of herbs and
25 supplements, would probably like to add this to their

1 armamentarium.

2 CHAIRMAN BRASS: Dr. Uden.

3 DR. DONALD UDEN: Yes. I want to follow
4 up on the comment made earlier about those people who
5 have cholesterols who are on the OTC from the 076 and
6 081 studies. Approximately half of them had
7 cholesterols which were greater than 240.

8 Was there any data that was collected in
9 those studies which showed that these people actually
10 took 20 milligrams or 30 milligrams, more than what
11 they were supposed to in reference to your question.
12 And were they allowed to do that?

13 I don't remember how, I mean, if you had
14 a bottle of pills, they could easily take two versus
15 punching out a self-dosing packet.

16 DR. SEGAL: The answer is that we don't
17 know the answer and the reason we don't know the
18 answer is because there was no diary collected. So we
19 don't really know in these trials how people actually
20 dosed. We just don't know the answer.

21 CHAIRMAN BRASS: Does sponsor want to
22 comment because I think it was in a blister pack and
23 I think it was --

24 DR. LAROUCHE: I do have data. It's true
25 that we don't have the daily diary cards which would

1 tell us whether or not people on an individual day
2 took more than one pill, but what we did have were two
3 things.

4 One was a survey where we asked people how
5 they dosed and in that survey nearly everybody said
6 that they dosed one pill a day for nearly every day
7 over the whole six months of the primary study. This
8 was a pharmacy study.

9 And the other thing that we had, which was
10 the objective pill counts, where we showed the percent
11 of the tablets that they actually took, we assumed
12 that they took them if they were missing from the
13 package when the package was returned, divided by the
14 number of days that they had the study drug in hand.

15 So, if the right number of pills was
16 missing for the number of days they had, that means
17 100 percent compliance.

18 So in the 722 people in the pharmacy trial
19 over six months, only 6 percent of people had pills
20 missing that would indicate up to 120 percent
21 compliance, which means that they could have taken as
22 much as one extra tablet every five days. So there
23 really was no evidence whatsoever to suggest that
24 people would be chronically overdosing.

25 DR. DONALD UDEN: And did the people who

1 had cholesterols over 240 know it at that time, that
2 the they had a 250 or a 260, when they were dosing?
3 They did didn't they?

4 DR. LAROCHE: In the pharmacy study we
5 didn't permit the people on the long-term usage who
6 were outside the eligible range and in study 81, we
7 did permit people on the four weeks of treatment, but
8 we don't have the same assessment available in that.

9 CHAIRMAN BRASS: Dr. Neill.

10 DR. NEILL: Primarily to provide comment
11 for FDA staff, nobody has discussed the need in the
12 OTC setting to monitor transaminase levels and whether
13 or not consumers can adequately do that. Sponsor
14 suggested that that's not necessary and I tend to buy
15 that argument at the 10-milligram dose.

16 The way the package is labeled, if a
17 patient has a cholesterol that drops, they say on that
18 10-milligram dose, nearly perpetuity, and if it
19 doesn't go down, then they are recommended to see
20 their doctor at which point apparently they'll have
21 appropriate evaluation done, which may or not include
22 transaminase testing.

23 As this question five, the global
24 question, is structured, I can't help but think that
25 the answer to that is yes, consumers will be able to

1 use lovastatin safely in the OTC setting given the
2 constraints of what it means to be in an OTC setting
3 and given the way that the label is set up.

4 I think that's not as much what we're
5 concerned about, but rather when it's not used in what
6 is recommended to be the OTC setting.

7 CHAIRMAN BRASS: I think the question
8 means in the actual use OTC setting, not as if they
9 follow it as was done in studies. I think this is the
10 question, is actually OTC use, do we have data to say
11 that consumers will in fact use the drug in a way that
12 is safe?

13 Other questions or other comments? If
14 not, do you want to vote on this one?

15 Okay, so the vote is on. Assuming that
16 lovastatin 10 milligrams is deemed adequately safe
17 when used for the proposed indication in the target
18 population, has the sponsor presented adequate
19 evidence that consumers will be able to use lovastatin
20 10 milligrams safely in an OTC setting?

21 All who feel that the answer to that
22 question is yes, please raise your hand.

23 DR. TITUS: Seven yeses.

24 CHAIRMAN BRASS: All who feel the answer
25 to that question is no, please raise your hand.

1 DR. TITUS: Six noes.

2 CHAIRMAN BRASS: Any abstentions?

3 Thank you.

4 The final question is, assuming that the
5 answer to question three, if you remember what
6 question three was, is yes, i.e., the sponsor has
7 provided sufficient information to support the safety
8 and effectiveness of lovastatin 10 milligrams for the
9 proposed indication in the target population, has the
10 sponsor provided sufficient evidence that lovastatin
11 10 milligrams can be used safely and effectively in an
12 OTC setting?

13 It seems to be a combination. So, this
14 seems to be a combination of four and five. So if
15 yes, are any additional studies needed post-approval,
16 what are the key messages that need to be conveyed?
17 I think we've discussed a number of those. If no,
18 what additional studies are necessary to support
19 approval for the OTC marketing?

20 I might just say that as one of those who
21 voted no on the safety, I would feel much better from
22 a safety perspective if we really had a no holes
23 barred, minimal intervention, actual use profiling of
24 what kind of consumers would actually buy this
25 product, including exposure to what we would consider

1 high-risk populations.

2 Not only high risk from a medical
3 perspective, but high risk from misuse because of
4 ethnicity or literacy.

5 And to understand with very minimal
6 intervention how well consumers can actually self-
7 select, particularly in the perceived risk
8 populations. Again, if somebody with a 250 versus 240
9 takes it, I don't think anybody is going to feel that
10 societal danger has been done.

11 Also, I would be very interested, and I
12 don't know how to get this information, but on whether
13 or not how this kind of availability modifies consumer
14 behavior. Is it in fact likely that a consumer will
15 be less likely to see a physician and enroll in
16 intensive care if this is available or isn't it?

17 I don't know the answer to that and I'm
18 not sure it's an easy question to answer, but I think
19 it's really pivotal in my assessment of what the risk
20 to benefit is.

21 Because we've talked about a potential
22 benefit in this population that is potentially of some
23 size, a risk that is probably small to exposure per
24 se, but we've all acknowledged that the benefit would
25 be greater if the patients saw a physician and

1 enrolled in a more aggressive program, even for
2 primary prevention.

3 And how we offset any movement from this
4 low-gain OTC population away from this bigger-gain
5 prescription population is a very difficult thing for
6 me to assess on a risk to benefit basis with the
7 information we've been provided today.

8 Are there other comments? Dr. Davidson.

9 DR. DAVIDSON: My concerns, number one,
10 that self-selection was not to my liking and I don't
11 think it is really a selection that I can feel good
12 about.

13 And number two, the overall follow-up at
14 18 months for patients taking the drug was not good
15 either. I didn't see any data on low literacy people,
16 minority people were excluded in some of the studies,
17 and that is not the target population that we're going
18 to address.

19 And therefore, I don't feel that this drug
20 should be approved for over-the-counter use.

21 CHAIRMAN BRASS: Yes, Dr. Uden.

22 DR. DONALD UDEN: To address your point
23 about healthcare providers and not seeking help. I
24 think what we're hearing is that people aren't doing
25 that now.

1 I think that that is the issue, is that
2 less than the fact that they would be moving away from
3 their practitioners, the fact that they're not going
4 to their practitioners, assuming this OTC population,
5 and that there is a vast unserved population that
6 would have exposure to this that isn't getting that
7 exposure by not seeing a physician.

8 CHAIRMAN BRASS: Yes.

9 DR. MOLITCH: I'd like to add to that in
10 an editorial fashion. If patients are not seeing
11 their physicians, I'd much rather see much greater
12 efforts expended by drug companies and healthcare
13 providers in getting the patients with higher
14 cholesterols, with higher risks, into get to these
15 healthcare providers than for the lot of expenditure
16 that is going to be put forward on this particular
17 aspect for a very low-risk population where a lot of
18 money is going to be spent for a very low decrease in
19 overall events.

20 Where that same money could be spent in a
21 high-risk population for a much better cost ratio.

22 CHAIRMAN BRASS: Other comments? Are
23 there other issues that the agency would like
24 additional input on or expansion of the discussion on?

25 DR. KATZ: We actually would like a vote

1 to that question.

2 CHAIRMAN BRASS: I'm sorry. Okay. It's
3 kind of complicated, because of the way we handled
4 three, but let's give it a try as they say.

5 Let me try put it this way. Let's vote on
6 the following question. Has the sponsor provided
7 sufficient evidence that lovastatin 10 milligrams can
8 be used safely and effectively in an OTC setting?
9 Let's just leave it at that.

10 All who feel that the answer to that
11 question -- I'm sorry, yes, please.

12 DR. EDWARD KRENZELOK: I'm sorry. I need
13 a clarification because we broke effectiveness down
14 into decreased LDL or evidence-based outcome, so are
15 we going to vote based on decreased LDL or on the
16 evidence-based improvement and outcome?

17 CHAIRMAN BRASS: What I would propose is
18 dealer's choice. And I will, to give a sense of the
19 agency of where we're coming down on effectiveness,
20 they know we don't think it's been proven that it
21 decreases cardiovascular events, so let's just avoid -
22 - I'm happy to do it twice, but I propose we do it
23 once with the wording as I read it. Is that
24 acceptable to the Committee?

25 DR. ORLOFF: And to the FDA as well.

1 That's fine.

2 CHAIRMAN BRASS: Okay. Yes, Dr. Neill.

3 DR. NEILL: Just in advance of making the
4 vote, a couple of comments have been made about the
5 potential public health benefit that would accrue by
6 virtue of the vast at-risk population in this low-risk
7 group that is going to benefit from this.

8 And comments have also been made that the
9 NCEP guidelines do not current recommend drug
10 treatment for this group. And I don't think any of us
11 should lose site of the fact that a change in those
12 guidelines could probably equally effectively result
13 in a public health benefit through the prescription
14 route without OTC consideration at all, as much as our
15 decision to step in front of NCEP if you will, or to
16 urge the adoption of that kind of guideline.

17 And so, in trying to consider in my own
18 mind whether or not how to think about the potential
19 public health benefits of this and whether or not we
20 would be doing a public health disservice by not
21 making this OTC. There are other avenues to address
22 that.

23 Lastly, there is an issue which hasn't
24 come up as much today and probably doesn't pertain as
25 much to this specific vote, but I feel like it's got

1 to get out at some point which has to do with the fact
2 that this medication in not very similar form, but
3 this medicine already exists over the counter and I
4 feel torn, as I'm sure the sponsor does, by the
5 realization that FDA is being asked to regulate
6 lovastatin as a drug while it's already available over
7 the market in a form that is not able to be regulated
8 by the FDA for a variety of reasons.

9 And I'm not privy to all of the court
10 issues that have gone on related to the regulation of
11 that, but there is a clear paradox when the FDA is
12 being asked to regulate lovastatin in an OTC fashion,
13 and we've spent a lot of time on this today, and on
14 the other hand, it already exists in a fashion which
15 the FDA can't touch.

16 At some level, obviously not here today or
17 by this group or FDA, but probably downtown, that will
18 need to be addressed. And regardless of how this vote
19 comes down, it won't change the fact that it's
20 available.

21 CHAIRMAN BRASS: I think the points you
22 raised are extremely important; however, I think we
23 have to be a little bit careful about how we
24 extrapolate certain information.

25 Somebody earlier said two wrongs don't

1 make a right and just because it's done wrong once
2 doesn't mean it should be wrong again.

3 Additionally, I'm not at all convinced
4 that a consumer who is quite comfortable taking an
5 herbal product for control of their cholesterol would
6 have any interest in an OTC product.

7 When my patients with that kind of
8 cultural bias, they have a blanket aversion to drugs,
9 period. And herbs and dietary supplements are a
10 completely different thing. And OTC drugs would be
11 just as abhorrent to them as going to a doctor and
12 getting drugs.

13 So I think our identification of all the
14 deficiencies in our existing societal ability to treat
15 high cholesterols has to be extrapolated very
16 cautiously to how the massive availability would or
17 wouldn't impact that problem and at what risk.

18 Are there other comments? Dr. Clark.

19 DR. CLARK: Yes. I just wanted to refer
20 back to the public comments this morning. All the
21 comments were in favor except one, but the reasons for
22 those comments had to do with the issues of increasing
23 access, issues related to patient and public becoming
24 more interested in self-help and participating in
25 their own healthcare, and issues of looking for better

1 strategies for cholesterol lowering in individuals and
2 populations.

3 And it just doesn't seem that those have
4 been issues that were important to any of these
5 deliberations here and I was just wondering if the
6 people who presented were kind of off base in terms of
7 what they were responding to.

8 Because those are important issues, but
9 they really haven't been a part of any of the
10 discussions here, and I'm not saying that's not
11 correct, but I would hope some response to those.

12 CHAIRMAN BRASS: I think your point is
13 correct, but I will point out that no data has been
14 presented to us to allow us to make those relative
15 judgements. And those go to some of the points your
16 hearing now about how availability, who would actually
17 use it, and at what potential benefit. Dr. Gilliam.

18 DR. GILLIAM: I was going to echo that
19 point somewhat in that although -- the point I was
20 going to make is that although there are going to be
21 people who are going to have cholesterols out of the
22 range and who probably shouldn't be taking this
23 product. But I guess I would rather see them take
24 something if they're not going to come in and see
25 whoever their healthcare provider is.

1 So I guess that's the main comment I want
2 to make there.

3 CHAIRMAN BRASS: And again, I think there
4 is broad agreement with that if we could assess what
5 the relative benefit of that versus a relative risk of
6 that will be. And that's where the absence of
7 specific adequate information in several areas has
8 been raised today, that makes that a challenging
9 conclusion for the Committee to draw. Dr. Johnson.

10 DR. JULIE JOHNSON: I have a question to
11 clarify what the question is going to be.

12 CHAIRMAN BRASS: I knew we should have
13 voted already.

14 (laughter)

15 DR. JULIE JOHNSON: Are we going to be
16 voting on something like if additional data are
17 provided is the product someday approvable?

18 CHAIRMAN BRASS: No. It's on the
19 information that has been presented to us today and
20 we've made suggestions as to already what type of data
21 would help us resolve some of the residual conclusion.
22 That's my interpretation. Does the agency agree?

23 DR. SLATER: The sponsor would not agree.
24 Excuse me doctor.

25 CHAIRMAN BRASS: I'm sorry.

1 DR. SLATER: I really truly would not know
2 how we could go about to gather the kind of
3 information you want to know.

4 Seriously, in the absence of actually a
5 post-marketing study where that 1-800 number for
6 example was used to collect the information, whether
7 the person did indeed get their cholesterol, whether
8 it was in range, out of range, whether they did call
9 their doctor or not.

10 In order to try and conceptualize the kind
11 of vast body of information that you folks are asking
12 for, is just not practical and doable.

13 CHAIRMAN BRASS: That's not the question
14 before the Committee now.

15 DR. SLATER: It's the same answer as you
16 are going to vote with or without suggestions. We
17 desperately need suggestions or we're going to say
18 this is just not a doable program, and that's really
19 what we're asking of you right now.

20 The only way we could get some of this
21 longer term information, demographic information,
22 etc., is through the actual marketed product. We
23 can't do a study.

24 CHAIRMAN BRASS: Well, I want to emphasize
25 that the Committee is advisory to the FDA, not to

1 sponsor and I think that we have heard a number of
2 suggestions that perhaps at a later --

3 DR. SLATER: You said there were
4 suggestions and I'm saying I do not have those
5 suggestions that I can translate into something
6 practical.

7 CHAIRMAN BRASS: Dr. Katz.

8 DR. KATZ: To answer your question as to
9 how do we want you to answer the question, the first
10 part of the question is really yes or no question.

11 If you answer yes, then you would go on to
12 part A. If you answer no, then you go on to part B
13 which would then give us some additional information.

14 DR. JULIE JOHNSON: Well, I guess my
15 confusion is that we essentially answered, or the
16 Committee answered no to question three in that we
17 answered no to the first part of question one, which
18 the way this is written, we wouldn't even answer
19 question six because we didn't answer question three
20 as yes. So that's where I'm confused.

21 DR. KATZ: Well, basically again, since
22 you actually really didn't answer question three, you
23 answered question one in two parts, and I want to make
24 sure for the record on question six that we really do
25 have your answer with regard to approvability. So

1 that's the distinction that I'm trying to make.

2 CHAIRMAN BRASS: Okay. So the answer to
3 your question is based on the currently available data
4 that has been presented to us. Has the sponsor
5 provided sufficient evidence that lovastatin 10
6 milligrams can be used safely and effectively in an
7 OTC setting?

8 All who feel the answer to that question
9 is yes, please raise your hand.

10 DR. TITUS: One yes.

11 CHAIRMAN BRASS: All those who feel the
12 answer to that question is no, please raise your hand.

13 DR. TITUS: Eleven noes.

14 CHAIRMAN BRASS: Abstentions? One yes,
15 eleven noes, one abstention.

16 Therefore, if no, what additional studies
17 are necessary to support approval for OTC marketing?
18 And I think several suggestions were made on both the
19 safety and on the efficacy side.

20 And let me just emphasize that on the
21 efficacy side, the suggestions were made in terms of
22 better defining and using LDL as a surrogate in
23 comparing to prescription use was one suggestion that
24 was made.

25 Are there other suggestions that have not

1 previously been discussed that people would like to
2 put on the table?

3 DR. DAVIDSON: I go back to my basics.
4 Number one, the lipid collection. Number two, a
5 compare with even lovastatin, but used in the manner
6 that we use it today and do the studies inclusive and
7 not exclusive.

8 DR. GELATO: I think it goes back to what
9 Dr. Clark was saying in that people who addressed us
10 this morning from the community were making a big push
11 for making this drug available to people who didn't
12 have access. And I'm not sure I really understand who
13 those people are.

14 It would help me to know what we're
15 talking about and who we're trying to target this for,
16 because when I look at the demographics that were
17 presented by the sponsor, those people that you showed
18 who were taking this drug were people who clearly had
19 access.

20 They had health insurance, they were
21 fairly well educated, and had fairly good salaries for
22 the majority of people.

23 So I think it is important to deal with
24 Dr. Clark's issue about who are the people who don't
25 have access and who are we trying to target here,

1 because that's what the other groups were making a
2 compelling case for, and I think it is a compelling
3 case, but it wasn't really answered in my mind as to
4 how that was actually going to be addressed.

5 CHAIRMAN BRASS: Dr. Davidson.

6 DR. DAVIDSON: The two groups that were
7 here this morning represent minorities. ABC
8 represented the African-American community and ICPS
9 represents the Latino in this community. And
10 obviously looking at what happened today, they were
11 not represented in the clinical trials.

12 And access to care, education for these
13 groups is clearly a necessity. And unless we partner
14 with the pharmaceutical companies, with the industry,
15 we're not going to get these people treated.

16 And I want to tell you, there are more
17 than 60 million minorities in just those two
18 communities living in this country. That's a big
19 market for the industry, but we need to see some
20 efforts directed to those communities in clinical
21 trials and in events that we can reduce in those
22 communities.

23 CHAIRMAN BRASS: Yes, sir.

24 DR. JENKINS: Yes, Dr. Brass. I'd like to
25 follow up.

1 Clearly this is a very difficult issue and
2 I think you heard Dr. Slater pleading for advice on
3 how they could do the studies that would make the
4 Committee feel comfortable to recommend approval of
5 this product at this dose OTC.

6 I think it was you earlier that
7 recommended something that you referred to as a no
8 holes barred, actual use, real world study, and I'm
9 wondering if you can provide the sponsor and us with
10 some more details of what that study would look like.

11 How would you do it? What endpoints are
12 you talking about looking at in that study? And maybe
13 we can use that information.

14 CHAIRMAN BRASS: Can I stop using my
15 government consulting rate and start using my other
16 consulting rate?

17 I think the issues are important here, had
18 having sat on this Committee for about forever, that
19 every time an open-label comprehension study is
20 presented, the issues are exactly the same.

21 The ability of a consumer, usually biased
22 towards high income, high literacy, Caucasian, to with
23 the label in front of them, read it, and check the
24 boxes on a multiple choice question.

25 And I do not feel personally that that

1 reflects how consumers actually buy these products.
2 And I think that you need a minimal cueing study so
3 that you're not biasing towards what the responses, or
4 even the indicational risks are, what the study
5 objectives are.

6 That you need to be able to have a
7 sufficiently broad population that is, if anything,
8 enriched in the risk groups, and as I said before, the
9 risk groups are broadly defined based on literacy as
10 well as medical problems. And challenge the
11 hypothesis that they will use it correctly, not do a
12 study biased to get the consistent with result.

13 And I think that in any other type of
14 scientific trial design, this kind of limited
15 challenging of hypothesis to conclude the hypothesis
16 is true, would not be tolerable.

17 DR. GILLIAM: Now that we've voted, I'm
18 confused. Because it seems to me that if you read
19 these questions, most of us voted yes on question
20 five, or it was six to five or whatever.

21 If you voted yes on that question, then it
22 logically seems to me that you would have to vote yes
23 on question number six, because it goes to consumers
24 that the sponsor has been able to say that consumers
25 will be able to use it in over-the-counter setting,

1 and then question number six says evidence that it can
2 be used safely and effectively. And it seems like
3 they are really the same question to me.

4 CHAIRMAN BRASS: Well, the issue was on
5 the effectiveness question, people did not vote yes.
6 So for safe and effective, the end statement captured
7 the either yes vote. Yes.

8 DR. TAMBORLANE: To get back to your
9 question about how you design a study. I would
10 suggest you could survey large groups of people and
11 find out whether they are interested in lipid-lowering
12 agents, what have been the obstacles to be involved
13 with using those drugs, are those people who felt that
14 they had an obstacle because they had inadequate
15 medical care? Those people could be given the drug
16 and asked to read it and see if they follow through.

17 I think there are ways to start with a
18 fairly hands-off way to try to direct people that way.

19 CHAIRMAN BRASS: Because even the type of
20 assessments for example, I think the issues about
21 whether patients are motivated to decrease their fat
22 in their diet and all those other types of things.
23 I've never had a patient come to my office who didn't
24 claim they were on a fat-free diet. That's just what
25 patients say. Dr. Temple.

1 DR. ROBERT TEMPLE: Well, I'm certainly on
2 a fat-free diet, except for those cookies. That was
3 just a small break.

4 There are really two sets of questions
5 that keep coming around and around. One is how sure
6 are we that the identified population would actually
7 benefit, and the other is, if they could, could they
8 use this drug properly in an over-the-counter setting.

9 Do you all have any sympathy for the idea
10 that the choice of dose is a problem? That is, using
11 10 milligrams when all your data is at 20? And that
12 focusing much more on an identified group with an
13 explicitly low HDL would be sort of a preliminary
14 basis for starting to do the studies to see whether it
15 could be used OTC?

16 Because at least then you might say, okay
17 I've got the TexCAPS population or something like it.

18 CHAIRMAN BRASS: Dr. Johnson.

19 DR. JULIE JOHNSON: Well, I sort of
20 thought about that and you can probably make two
21 arguments and you can make one argument that it's
22 already been documented in a large randomized placebo-
23 controlled trial that those people, the AFCAPS
24 population, should be treated and they should be
25 treated with 20 to 40 milligrams to a goal of less

1 than 110. So how do you ethically do that?

2 As the discussion went on today I was sort
3 of struggling on today with should we recommend that
4 their label include an HDL criterion, but then if you
5 do that, you're really capturing the AFCAPS population
6 and you're treating them less effectively than the
7 AFCAPS study. So that's I think the difficult part.

8 DR. ROBERT TEMPLE: Well, the second part
9 is in some ways the question. There are people who
10 come before you and say, well yes, maybe the
11 compliance won't be as good as if someone's actually
12 with his or her physician, but I'll treat so many more
13 people for some slightly mysterious reason that I'll
14 end up getting more of those people treated than I
15 otherwise would, and that might be an added benefit.

16 I guess what strikes me then is that at
17 least you're talking about OTCness again and you're
18 not arguing about whether you have any effectiveness
19 of the regimen, you're arguing about whether it can be
20 give in an OTC environment, which is at least
21 conceivably studiable.

22 Whereas for reasons the company gave, they
23 can't study the less ill populations because they'd
24 have to study 200,000 people, which is another way of
25 saying the benefit is very small, of course.

1 CHAIRMAN BRASS: But obviously a
2 positively controlled study like that can be done
3 ethically in that kind of situation, but the design
4 would be -- I would submit if you compare 10
5 milligrams over the counter to that, you already know
6 the answer is negative, because 20 milligrams didn't
7 work. Half the patients needed to be titrated to 40.

8 So that if you know that 20 milligrams
9 doesn't work at a fixed dose to achieve the same
10 efficacy, then you're really trying to replicate the
11 titration in the OTC setting as well.

12 DR. ROBERT TEMPLE: Well, actually focus
13 it on a population that has a poorer HDL, because
14 there you have the data and it's going to be very hard
15 to get the data in the very high HDL population, for
16 the reasons that everyone has been given.

17 But it seems to me the implication of that
18 hasn't been accepted, which is that the benefit is
19 extremely small, probably not demonstrable in any
20 real-world study, which makes one ask whether that's
21 a really good thing to do.

22 But in the AFCAPS population, there is
23 some evidence that it is a good thing to do, otherwise
24 we wouldn't have approved it for the Rx labeling.

25 So the question then could become can you

1 deliver that treatment in an OTC setting? I don't
2 think I know what the answer is, but at least that
3 seems like a reasonable question.

4 DR. ORLOFF: I think just to expand a
5 little bit, frankly, one of the questions that we
6 never really did get to in a broader sense today was
7 the viability of hypercholesterolemia generally as an
8 OTC disease. In the past we had stated that it
9 wasn't.

10 To expand on Dr. Temple's proposition,
11 we've talked today about limited indication for use in
12 a limited dose. What about the possibility? How do
13 people feel about the expansion of the indication and
14 the expansion of dose?

15 We have a lot of indications for the use
16 of cholesterol-lowering drugs that are contained in
17 the prescription labeling.

18 Again, to harken back to what Dr. Temple
19 just said, can that, can those benefits, be accrued
20 with an acceptable level of risk in an OTC setting?

21 DR. GANLEY: I just want to follow up on
22 that because I think one of the differences in the
23 paradigm of treatment has been I think of a set dose
24 rather than a titrated dose. And I guess my question
25 is, is 40 milligrams or even 80 milligrams, an

1 acceptable dose as an OTC dose and if it is not, why
2 is it not?

3 You've already voted on 10 milligrams as
4 a safe dose. We've heard information from the sponsor
5 that liver disease is very rare. Rhabdomyolysis is
6 likewise rare. And even if you give a drug that
7 inhibits the metabolism, it's still rare. So why
8 isn't 40 milligrams or 80 milligrams?

9 And it also brings into play the issue
10 that was brought out somewhat today and also in the
11 Part 15 hearing we had whereby it's not just this
12 population that may need treatment, it's the
13 population that clearly would benefit here that needs
14 treatment. Is that an OTC population?

15 And could you come up with a paradigm
16 where there is a titration in an OTC setting where you
17 could carry it to 40 milligrams or 80 milligrams? And
18 if the drug is so safe, why not just start at 40
19 milligrams?

20 CHAIRMAN BRASS: Dr. Clark.

21 DR. CLARK: This being my first attendance
22 at one of these meetings, I feel I can ask this
23 question.

24 As Dr. Orloff pointed out this morning,
25 this is the third time I guess this question has come

1 before this Committee in the last five years, and I'm
2 curious as to whether or not there is movement in some
3 direction or if these are just different issues each
4 time as it relates to cholesterol lowering in OTC?

5 CHAIRMAN BRASS: I think we are about to
6 start on another meeting right here.

7 (laughter)

8 But I think the questions you've raised
9 are important, but if I could extrapolate from what's
10 been discussed any my own opinions will obviously
11 contaminate this, I think you're hearing some things
12 about where the bar would need to be placed in order
13 to convince the Committee about that. And that bar
14 would be no different for 40 or 80 versus 10.

15 In fact, the ability to convince the
16 Committee of cardiovascular endpoints at different
17 doses and at different populations would probably be
18 a lot easier.

19 The ability to convince the Committee that
20 the OTC population would use it the same way, to
21 replicate that efficacy, as has been seen in the
22 prescription setting, I think would still be there,
23 and many of those concerns would be there. And the
24 need to define the safety in a real OTC use would
25 still be there.

1 So I think the themes are recapitulated
2 and what you've done and your hypothesis would be to
3 make it easier to extrapolate the benefit and more
4 challenging to show that the OTC population replicated
5 that benefit in safety. I don't know what other
6 members -- Dr. Johnson.

7 DR. JULIE JOHNSON: Since you're asking
8 sort of broad generic questions, I think this came up
9 multiple times at the Part 15 hearing. I mean, this
10 is also very possibly a category that fits very well
11 in this proposed third category of drugs which are
12 dispensable by a pharmacist, but kept behind the
13 counter and monitoring could be done with these little
14 things that they have sitting on their counter. And
15 obviously that is not in our purview and maybe not in
16 the FDA's. I don't know if that's a legislative thing
17 or not.

18 But that's another potential, especially
19 if you were going to be considering higher doses or
20 methods that require dose titration that I'm not
21 convinced patients could undertake.

22 DR. DAVIDSON: My concern is
23 cardiovascular disease in the United States remains a
24 very important issue. It's expensive. It's
25 increasing or at least it is not declining.

1 And my concern is if we allow uninformed
2 people to take a drug believing that that drug is a
3 miracle drug that is going to prevent events in the
4 future, knowing that no drug, no statin, will prevent
5 100 percent of the MIs, I think we are going to be
6 giving a message that is not a clear message to the
7 community.

8 It has been stated clearly. There are
9 some things we need to do. We need to do education to
10 the whole country. Nutrition remains a very important
11 arm of this part. Exercise remains a very important
12 arm of this part. Maybe aspirin use is as important
13 as in the statins. Because if a statin will lower the
14 MIs by 90 percent, then I think that over the counter
15 with the safety that they have is good.

16 But the consumer, and I may be wrong, may
17 not be ready to tell them, that this is a drug, nobody
18 is going to follow up with lipids, nobody is going to
19 follow up with any side effects. You also showed that
20 the higher the dose, the more side effects we have.

21 Then I think we need to be very careful
22 when you ask me if we go to a higher dose, is that
23 really an over-the-counter medication and your first
24 question is, is actually dyslipidemia an over-the-
25 counter treatment. It's not just cholesterol, it's

1 triglycerides, it's LDL, it's total cholesterol, and
2 how high is the LDL, and the whole thing.

3 It is a lot more difficult to assess the
4 lipid profile of a patient than just looking at LDL.

5 CHAIRMAN BRASS: Yes.

6 DR. MOLITCH: In addressing the issue of
7 dose titration by patients themselves going up to 40
8 or 80 milligrams per day. For those of us who
9 actually see patients and prescribe these drugs in
10 practice, every time you try to measure something and
11 then get them to increase the dose because their LDL
12 is not below 100, the patients resist doing it.

13 They complain, they think, well my
14 condition is worsening, I have to take more drug, and
15 so either they don't do it sometimes or if they'll do
16 you have to spend 10 or 15 minutes visiting the
17 patients why they need to do so.

18 And it's actually very difficult to
19 titrated doses upwards, even when there is a very
20 clear rationale, whether it's for cholesterol or blood
21 pressure medications or oral hypoglycemic agents for
22 diabetes control. Every time you increase the dose
23 the patients get worried and there is a resistance
24 that sets in.

25 So, it would behoove you I think to really

1 be able to show that patients can self-titrate
2 themselves upwards without a physicians assistance
3 when it's already difficult to do even with a
4 physician's assistance.

5 DR. GANLEY: I think in response to that,
6 we already have drugs were people self-titrate.
7 Granted they are based on symptoms. For example, we
8 have ibuprofen products where they will take one or
9 two tablets.

10 And I think that my interest is that we
11 should try to maximize benefit here and one way to do
12 that is to have a goal for people. It's easier with
13 symptoms because you know what the goal is. It's a
14 little more difficult here, but maybe not impossible
15 to achieve.

16 So I think it becomes an important
17 question. And if a consumer's fears are unrealistic
18 in your view, then there is a message that possibly
19 could get out if you had an OTC product that started
20 at 40 milligrams and went to 80 milligrams. Using
21 some paradigm that was understandable.

22 And I think it really comes down to what
23 was mentioned previously about what the absolute
24 benefit is and what is the risk of a higher dose. So
25 that becomes very important in looking at that

1 question.

2 DR. GRADY: Just to follow up on that. I
3 think what bothered me most about this whole regimen
4 was that the dose had been taken so low and the
5 population chosen is so low risk, that then you have
6 to begin to wonder if there is really going to be any
7 benefit. And if there is not much absolute benefit,
8 then any absolute risk will outweigh that.

9 So I actually like the idea of thinking
10 about over-the-counter use of somewhat higher doses,
11 particularly if it could be monitored using a protocol
12 by nonphysician personnel. Because it is just a
13 protocol and it doesn't really require a physician to
14 do this.

15 In fact, I think probably nonphysicians
16 could do it better if there was some requirement for
17 periodic monitoring.

18 DR. DAVIDSON: The problem is that over
19 the counter does not allow you to have a protocol.

20 CHAIRMAN BRASS: Anything else from
21 anybody? In case anybody missed anything, we are
22 going to do this all again tomorrow.

23 (laughter)

24 Let me close by thanking very much the
25 sponsor -- or wait a second, wind it out.

1 DR. TITUS: I'd appreciate before you all
2 leave to turn in these red books to me or Kathleen and
3 if you talk to Kathleen or myself, we have some dinner
4 options available.

5 CHAIRMAN BRASS: Let me thank the sponsor
6 and their representatives, the agency and their
7 representatives, and all the Committee members for
8 their excellent input. I apologize we ran 28 minutes
9 late, but it was all those extra questions you threw
10 in.

11 We are now adjourned.

12 (Whereupon, the foregoing matter concluded
13 at 5:29 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript in
the matter of: JOINT MEETING OF THE NONPRESCRIPTION
 DRUGS ADVISORY COMMITTEE AND THE
 ENDOCRINOLOGIC AND METABOLIC ADVISORY
 COMMITTEE

Before: FOOD AND DRUG ADMINISTRATION
 CENTER FOR DRUG EVALUATION AND RESEARCH

Date: THURSDAY, JULY 13, 2000

Place: BETHESDA, MARYLAND

represents the full and complete proceedings of the
aforementioned matter, as reported and reduced to
typewriting.

Rebecca Davis

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