

1 titrated to goal if these agents weren't available in a
2 fixed-dose combination.

3 DR. TEMPLE: Now, how is that different from
4 starting on 40, which is what the recommended starting dose
5 is, and having stopped that and go buy the 80 milligrams or
6 take two of them or something? You think this makes it
7 materially worse because stopping the aspirin and going to
8 the drug store and getting a few aspirin is really hard.

9 DR. NISSEN: Yes, I do.

10 DR. BORER: And I would agree with that, and
11 I'd even amplify on it but I don't think I have to.

12 Tom?

13 DR. FLEMING: I'd like to probe on this a bit
14 more as well, maybe somewhat along the lines of what Bob
15 was just asking.

16 Quite frankly, I'm inclined to vote yes in
17 question 9 unless there is a substantial reason given in
18 question 8 to there being a concern with this packaging,
19 and in the context of question 7, the way I've been
20 thinking about this is what's this all about. Why are we
21 considering this packaging?

22 It needs to be at least reasonably well
23 motivated that there will be an enhanced likelihood of
24 achieving the most favorable benefit-to-risk profile that
25 these agents are capable of providing should you have a

1 more optimal level of adherence. There needs to be a
2 perception or a reality, better than that, that we have
3 effective agents here that are being underused and as a
4 result, globally we're not achieving the level of clinical
5 benefit that they could potentially provide. If that's not
6 true, we're done.

7 Now, if in fact that's true, and presumably
8 that would be argued to be true in the sense that when you
9 have a packaged delivery, you're going to make it more
10 convenient and you're going to have a higher level of
11 consistency and accuracy in the delivery of these doses to
12 a larger fraction of the population than currently is
13 getting access to this. That's the pro argument and we've
14 heard that from the sponsor.

15 The con argument that we're hearing that also
16 seems to be relevant is there's a "yes but." There are
17 circumstances in which this packaged delivery can be
18 nonoptimal, examples being there are certain types of
19 patients that shouldn't be getting antiplatelet therapy and
20 it may be, in fact, not recognized as readily when they are
21 taking a single tablet, or maybe they're getting a
22 nonoptimal antiplatelet agent. Or it may be that we're not
23 achieving an adequate level of targeted goal of lipid
24 reduction and it may become less likely that we would have
25 an altered dose or altered selection if people are choosing

1 this. I see all of those as relevant concerns, but it is
2 true, somewhat, that when you label things, or at least
3 when you make it as clear as you can that this
4 intervention, this particular package combination isn't
5 necessarily the right choice for all people, that some of
6 these concerns can be offset by intelligent use of this.

7 So, what I'm left with in the end is the
8 subjective weighing out of what are the benefits that we're
9 going to get when we're using it correctly and it's going
10 to give an enhanced, widespread use of agents that have
11 potential of delivering benefit but they're being
12 underutilized against these instances that we've given
13 where there are concerns. The fact that there are concerns
14 doesn't mean that the benefit-to-risk, so to speak, is
15 negative.

16 What I'd like to get a sense of from the
17 committee is, is there really an unmet need that's
18 sufficiently substantial such that if this is more
19 convenient, we really will achieve a higher level of
20 adherence and thereby a better benefit-to-risk in the
21 broadest population, but that there are these concerns and
22 in fact they're real but they won't counterbalance the
23 benefit, or are these concerns so real that they will give
24 us no net gain? That's the answer I'd like to hear.

25 DR. BORER: Tom, let me begin responding to you

1 by pointing out something. You said get these agents to
2 people. I don't believe we're talking about improving
3 compliance with two agents. I think we're talking about
4 compliance with one agent. The frequency of prescription
5 of statins I don't think is going to be altered one bit by
6 making this combination available. The associated use of
7 aspirin may well be increased. I mean, it may or it may
8 not be. I don't know, but it might be. I don't think the
9 use of statins is going to be altered at all. So, it may
10 be that we might alter the use of aspirin by providing the
11 combination.

12 I think, though -- and I'd like to hear from
13 everybody else to respond to Tom as well -- that the sense
14 of the people who have spoken, about this among the voting
15 members of the committee, is that perfect is the enemy of
16 good, and we don't know what perfect is, and being on some
17 statin, if you have any of the conditions for which the
18 drug is indicated, is better than being on no statin.
19 We're not going to alter the statin part of this equation
20 here.

21 What we are going to do, however, we believe,
22 by limiting the dose range of the combination, is making it
23 very likely that people will use this dose even if, left
24 unfettered, their judgment would cause them to use
25 different doses for targets that they may wish to achieve

1 based on clinical guidelines or whatever else. And it's
2 not that they couldn't make the change, but that it becomes
3 so inconvenient and costly to make the change that they're
4 unlikely to do it and that the patients may not benefit
5 from that.

6 Now, Beverly and Steve and the others here,
7 maybe you may want to add to that.

8 DR. NISSEN: Well, I think you said it very
9 well. Tom, let me see if I can help you with this.

10 There are two sides to this equation. Will the
11 combination improve safety or make safety more of a
12 concern? We're talking about weighing, pluses and minuses.

13 I think for that one it's pretty clear to me that the
14 likelihood that people will get aspirin inappropriately and
15 therefore raise a safety problem goes up not down. I think
16 the likelihood that a primary prevention patient who
17 shouldn't get aspirin will and the chances that a patient
18 will get aspirin when having a surgical procedure that
19 shouldn't will are both worse with the combination. So, on
20 the safety side, it's not a plus.

21 What about efficacy? Efficacy would mean that
22 more patients that ought to have co-administered aspirin
23 would and that more patients would be more likely to get to
24 those lipid targets that we've spent the last 7 or 10 years
25 trying to get people to follow. And I have concerns that

1 the net balance on the efficacy side will be worse. Yes, a
2 few more patients may get aspirin, but the burden of then
3 having to go through this process of stopping a combination
4 product, switching to a different statin, and
5 co-administering aspirin will be enough of an impediment in
6 primary care and in other settings that fewer patients will
7 actually get to the goals that we want, and so therefore,
8 this combination will have an adverse effect on overall
9 efficacy.

10 So, I think for me it loses on the safety side
11 and it loses on the efficacy side.

12 DR. THOMPSON: Jeff, I'm a non-voting member,
13 but can I comment?

14 DR. BORER: Yes, sure, Paul.

15 DR. THOMPSON: Because I'd like to make two
16 comments.

17 First of all, I always tell people that there
18 are two devils in this world. There's the devil you know
19 and there's the devil you can speculate about. When we
20 look at the devil we know and we look at slide D-13, we see
21 that among those patients -- now, this is 1999 data -- with
22 known cardiovascular disease, only 51 percent reported that
23 they were taking aspirin or an equivalent. So, that's a
24 large gap. And we also know that 15 percent of those who
25 said they were taking aspirin were taking something else.

1 They were taking a non-aspirin compound. So, I think we're
2 actually speculating a fair amount about things that are
3 possible, devils that we're actually imagining, as opposed
4 to facing devils that we can see and have data in.

5 Now, a couple other small comments. We're
6 talking a lot about the safety of withdrawing a statin, for
7 example. I do that in my lipid clinic all the time because
8 people always doubt whether the statin is responsible for
9 their effect. So, I stop it to show them that indeed the
10 statin was effective.

11 We're also talking about the negative stuff of
12 aspirin in primary preventions. Well, it's news to me.
13 It's one of the few things I do for myself. I think most
14 cardiologists do take aspirin for primary prevention. So,
15 perhaps there's some data that wasn't presented that I
16 didn't know.

17 Then finally, what I always do and I tell my
18 children to do when I have to make a decision is I make up
19 a list of pros and cons, and I'm glad to share that with
20 you, if you'd like. But I've listened to the cons during
21 the day that aspirin might be taken by those who are at
22 risk to bleed, and there are all those sorts of risks. But
23 when you take and you make up your benefit-risk thing, even
24 with the fact that convenience for a patient is a benefit
25 -- I thought this was actually a slam dunk when I read this

1 stuff at home before coming here. I had no idea.

2 But when you look at the pros and the cons, I
3 find it hard to worry so much about these devils unknown as
4 opposed to the devils we actually see in the data and the
5 efficacy of the combination shown from the meta-analysis,
6 which we all agreed that we liked.

7 I'll go through my pros and cons, but I don't
8 want to take more time. I'm a nonvoting member, but I've
9 listed to everything such as that you lack flexibility.
10 But that lack of flexibility with a 40 milligram dose may
11 get doctors start with 40 milligrams as opposed to 20
12 milligrams. So, for most of the things we've talked about
13 as a negative, there's also the potential benefit.

14 No data on aspirin effect when given together,
15 but actually we do have some data. It looks like it
16 decreases the event rates. And this was the stuff on
17 platelets. In other words, people were talking about the
18 fact that there was no effect on the platelet effect.
19 Well, there's no in vitro studies, but there are in vivo
20 studies showing that that combination looked better. Now,
21 if you give me a choice between some Bademan's platelet
22 chamber versus some human being, I'm going to take the
23 human being studies.

24 So, I've listened to the two sides of it, but
25 I'm surprised a little bit.

1 DR. BORER: Tom, did you have some comments
2 here?

3 DR. FLEMING: Jeff and Steve, I wanted to just
4 follow up for clarification on your insights.

5 I understand, Jeff, from what you're saying is
6 that you see the most substantive impact of this would be
7 potentially increased adherence to the aspirin, that the
8 lipid-lowering intervention will essentially, in terms of
9 its overall coverage, largely stay the same.

10 DR. BORER: Yes. Anything else would have to
11 be a result of marketing, and I don't think we can make any
12 guess about the impact of marketing, how it's going to be
13 done, or whatever. But logically there should be no impact
14 on the use of the statin. It really should be only on the
15 impact of the use of the aspirin.

16 DR. FLEMING: So, if I go with that, Steve,
17 what I heard was a concern in terms of the safety side in
18 particular being that if there isn't an as flexible an
19 adjustment of the regimen for a lipid-lowering agent, that
20 could have adverse effects on efficacy and safety.

21 DR. NISSEN: No, I'm sorry. The safety issue
22 related to the aspirin. I'm very comfortable with the
23 safety of pravastatin and, frankly, the other statins as
24 well.

25 DR. FLEMING: All right. So, basically it

1 would be a concern about potential loss of efficacy on the
2 lipid-lowering side, the statin side. When we see data, as
3 we were just referred to, D-13, and we see estimates of
4 about 50 percent underuse of aspirin, even though I
5 appreciate that there are settings you've described where
6 aspirin use could be inappropriate and hence larger use
7 could lead to then some instances of adverse effects, if it
8 truly is 50 percent, isn't the up side for increased
9 adherence to aspirin far greater than the down side?

10 DR. BORER: I don't know. I really don't know.

11 First of all, we have no idea what the impact on aspirin
12 use would be. We heard that in Sweden there wasn't much
13 impact, not that those are primary data, and yes, this is a
14 convenience product.

15 DR. FLEMING: I am persuaded by what was said
16 earlier and that is if you make this available and it's not
17 in fact used, then that's a marketing issue. That's not an
18 issue as to whether this had the potential of providing
19 benefit. In fact, there's no harm, in a sense, done if you
20 make this available and no one uses it. We just didn't
21 provide any benefit.

22 My concern is if we make this available and it
23 is used, is this in fact going to achieve more net benefit
24 than harm, and the benefit would allegedly be, if I focus
25 on the way you think this is going to go, Jeff, it has the

1 potential at least of substantially increasing adherence to
2 aspirin which, if we believe the efficacy data, has the
3 potential of providing meaningful benefit on major events.
4 But then there is the offsetting aspect that in some of
5 these cases, there may be some safety concerns, and in the
6 lipid-lowering case, there may be lack of as effective
7 adjustments that could provide some offsetting.

8 So, is that the benefit-to-risk that we would
9 have to say when we --

10 DR. BORER: As far as I'm concerned, you've
11 pretty much noted the elements, and I would go one step
12 further. I'd be a lot happier, because I think the problem
13 would be obviated, if the sponsor provided pravastatin at
14 several doses with aspirin attached to it so that I could
15 give the dose that I want to give.

16 DR. NISSEN: We don't know what percent of that
17 50 percent not on aspirin also require co-administration of
18 statins. You understand that that data is not statin data.
19 That's aspirin data. So, there's an unknown here, and
20 that is how many of those people would be even eligible for
21 a combination product, and we have not been provided with
22 any information about that.

23 DR. FLEMING: A very important point. Is there
24 anybody that has that data? If this 50 percent doesn't
25 apply to our population and we need to know what percent of

1 the people on statins are not using aspirin, which is very
2 relevant.

3 DR. ARTMAN: Just go back to D-10, the sponsor
4 showed us data from 167,000 patients who had had an MI at
5 discharge, and 77 percent of them were receiving aspirin
6 and only 37 percent were receiving statins. So, I don't
7 see this as an underutilization of aspirin. I see it as an
8 underutilization of statins. And I think the sponsor is
9 probably not going to go out promoting aspirin. They're
10 going to go out promoting pravastatin.

11 DR. BORER: Which they could do anyway.

12 DR. ARTMAN: Which they could do anyway.

13 You know, this was prefaced to us with this
14 treatment gap and it's a public health issue, and it's not
15 because the drugs aren't available. These drugs are
16 available. It's educating the physicians and, these days,
17 educating the consumers directly. So I think, Tom, this
18 maybe is more reflective of the proper patient base.

19 DR. FLEMING: I was going to throw something
20 out here because part of where I'm struggling here is I
21 prefer to be looking at quantitative results and we're
22 having to speculate and that's somewhat unavoidable.

23 We had data presented to us which wasn't
24 certainly as reliable as what we would have had from
25 randomized trials, but it's the best evidence at least that

1 I have that I can use in a subjective judgment here that
2 says you're going to have on the order of 25 to 33 percent
3 reduction in major events with proper administration of
4 these interventions. If in fact making an intervention
5 that's more convenient does allow for a 25 percent -- and
6 that's a pretty substantial increase -- but a 25 percent
7 increase in adherence from 50 to 75 or whatever, that leads
8 to what one could at least speculate a pretty substantial
9 reduction in the overall rate of occurrence of some of
10 these events.

11 On the other hand, there are these down sides
12 that occur that relate to safety. It has to be a pretty
13 strong argument I would think, though, that those down
14 sides would be so substantial that they could offset this
15 potential for a very substantial gain by having greater
16 adherence to effective agents.

17 DR. BORER: To preempt Beverly for just one
18 second here and to try to answer your question, I can't
19 answer the question.

20 As it was presented, I recognized the same
21 concern that Steve just verbalized, that is, that we were
22 shown the gap for all aspirin users. If you look at the
23 data in the book from LIPID and CARE -- it may not be
24 representative but that's what we've got -- pages 14 and 16
25 in the briefing book, patients were randomized to

1 pravastatin or placebo. They may have been on aspirin. 83
2 percent of the patients in LIPID were on aspirin; 84
3 percent of the patients in CARE were on aspirin. That's a
4 gap of 16 to 17 percent, not 49 percent.

5 And I'll tell you my opinion. I can't
6 substantiate it. My opinion. Once somebody is taking a
7 statin drug, their perception of the importance of drug-
8 taking is heightened, and I think it would be more likely
9 rather than less likely that they would take their
10 concomitant aspirin. I don't know if that's true or not,
11 but that's the way I would interpret these data.

12 DR. FLEMING: Let me reiterate my question then
13 from five minutes ago, which is if it's appropriate to
14 suggest that this 50 percent underuse of aspirin isn't
15 relevant to our context, we need to know, in the context of
16 somebody who would be on lipid-lowering agents, what is our
17 best estimate of that. I understand, from the clinical
18 trials for aspirin, when you have people joining a clinical
19 trial to be randomized to a lipid-lowering agent, 80
20 percent were using aspirin, but does that represent the
21 real world, which was my question. And then we had
22 reference to data from D-10.

23 DR. HIRSCH: Tom, you're not going to get an
24 answer to your question. There are various surveys with
25 various aspirin use rates in different populations, and you

1 can quote figures from 50 to 90 percent. Somewhere between
2 70 and 80 percent is probably accurate. And you're not
3 going to be able to make your decision based on that.
4 Although you'd like that hard data, sorry, you're not going
5 to get it today.

6 And I'm going to charge in and make an
7 impassioned plea here. I'm someone, Tom, who also deals
8 with this public health issue of use or not use and filling
9 the gap in underuse of medications. I'm a little surprised
10 at us today. I'm a little surprised that we're going to
11 try to make a decision at this last minute to try to fill
12 this gap with this single product combination because any
13 hope of us changing the outcome of use of aspirin and
14 lipid-lowering agents in America with this decision -- that
15 happens with very long, large-scale NIH, American Heart
16 Association 5- and 10-year, Healthy People 2010 plans. It
17 doesn't happen in a deliberation like this.

18 I would like to constrain the conversation a
19 little bit and bring it back down to, again like you were
20 saying earlier, is there some evidence of efficacy, what is
21 the safety issue, and do we think physicians can prescribe
22 more or less appropriately, never perfectly.

23 And with that, Bev, go ahead.

24 DR. LORELL: Thank you.

25 I think that in thinking about the data that

1 we've seen today, we've seen very compelling data from the
2 meta-analysis that the use of Pravachol plus aspirin is
3 efficacious. But I think a very interesting point is that
4 the use of aspirin in the trial data that we have to look
5 at to make our decision was discretionary. It was a high
6 frequency of use that we saw, but it was discretionary and
7 what people were really doing in those trials was taking
8 two separate pills.

9 I am concerned about the issue that having a
10 single fixed dose carries a risk, as was put well by one of
11 my colleagues, of increasing the likelihood of under-
12 treatment with statins, but I think that my much larger
13 concern that I had not even thought about until I heard the
14 discussions today, is the very real risks of packaging a
15 potent antiplatelet agent with something else. And I would
16 go on record as saying that I have grave concern about
17 packaging aspirin, clopidogrel, or any other antiplatelet
18 agent with anything, whether it be a beta-blocker, an ACE
19 inhibitor, you name it. I use these drugs every day in
20 very high-risk patients. Aspirin is a powerful drug. It
21 carries risks of bleeding. Patients and doctors have to be
22 extremely attentive to its use and the subtle nuances of
23 when to temporarily stop and when to restart it. So, I
24 think my largest concern is I don't think the issue of
25 convenience is outweighed by the very real risk and lack of

1 data about packaging a potent antiplatelet with something
2 else. To me that's a very major issue.

3 DR. BORER: Blase, do you have any last comment
4 here?

5 DR. CARABELLO: No.

6 DR. BORER: Then let's move on to question 9.
7 We'll go around the table because this is a vote that has
8 to be counted, and we have to have a verbal statement.

9 Do you recommend approval of a fixed-dose
10 combination product of pravastatin plus buffered aspirin --
11 I assume the product that we've been given, which is the
12 doses -- yes, right?

13 DR. LIPICKY: Yes.

14 DR. TEMPLE: Jeffrey, one thing. We didn't
15 think of this. You ought to address the question of
16 whether it would be different if they made it available
17 with two doses of pravastatin, which they may not want to
18 do, but which is certainly possible.

19 DR. BORER: Alan, why don't you start?

20 DR. HIRSCH: Am I'm allowed, Bob, to answer
21 your first question first? I mean your dosing question.
22 Say yes.

23 DR. LIPICKY: [Inaudible.]

24 DR. BORER: Why don't we answer this one first?
25 Then we'll go around the room and ask the second one.

1 DR. TEMPLE: That would be okay. Would your
2 answer be different if they had an 80?

3 DR. LIPICKY: If you say no, then you can ask
4 what if you had two doses of pravastatin, would that be
5 good?

6 DR. HIRSCH: I'll need to explain later. I'll
7 say no.

8 DR. BORER: Let's start with Dr. Kreisberg.

9 DR. KREISBERG: No.

10 DR. LORELL: No.

11 DR. BORER: That was a no from Beverly.
12 Susanna?

13 DR. CUNNINGHAM: No. I'd really like to have
14 the information that allowed me to vote differently. I
15 would like to know that this was safe and that people
16 wouldn't be put in trouble, and I'd like to know that this
17 actually helped people to take their drugs more. We don't
18 have that information. I'd like to have something that
19 says if it were available as a combined, one, people would
20 take it more often. I don't have that. I hate having to
21 guess, and so I'm going to say no.

22 DR. BORER: Mike?

23 DR. ARTMAN: No.

24 DR. BORER: Tom?

25 (Pause.)

1 DR. KREISBERG: Yes or no.

2 (Laughter.)

3 DR. FLEMING: Well, there is a third and I'll
4 take that option. I'm to abstain from this. I actually
5 was inclined to vote yes, and I've been persuaded by a lot
6 of comments over the last 20 minutes that this is extremely
7 difficult.

8 Basically my sense is that if it is, as I would
9 have thought, much more plausible than I'm hearing, that we
10 really would enhance the overall adherence, then I would
11 think that the potential for benefit exceeds the very real
12 and relevant concerns. But what I'm hearing from my
13 clinical colleagues, who have much better insight than I do
14 about the actual real-world reality of this, is it's not
15 very likely we're going to have enhanced adherence, and if
16 that's the case, then I don't believe that it would be a
17 positive step. So, in the absence of being able to make an
18 informed judgment about that, I think I'm going to abstain.

19 DR. BORER: Blase?

20 DR. CARABELLO: Yes.

21 DR. BORER: Steve?

22 DR. NISSEN: No.

23 DR. BORER: And I'll vote no. So, we have 7
24 no, 1 yes, 1 abstain.

25 Now let's go on to the next issue, which is the

1 one that Bob just asked, and I'm going to change the
2 question just a little bit. What if we had not two doses
3 but a broader range of pravastatin doses? I don't want to
4 pick the doses, but what if we had a broader range of
5 pravastatin doses available together with aspirin? Would
6 that change the vote?

7 Alan, why don't you start?

8 DR. HIRSCH: Yes, and the reason is because
9 pravastatin is safe and effective, aspirin is effective and
10 rather safe. Actually the biobehavioral issues of how
11 patients take drugs and physicians prescribe them are the
12 main ghost in the room. That's what this is all about.
13 For that, I think with a dose range, I would certainly have
14 voted yes.

15 DR. KREISBERG: I'll vote no and the reason
16 that I'll vote no is that the only alternate dose is 80
17 milligrams, at least that's what I'm hearing. And that
18 adds an additional 3 percent LDL cholesterol lowering, and
19 consequently I don't think that's enough of a therapeutic
20 option to make that an attractive one. So, my answer is
21 no.

22 DR. BORER: Beverly?

23 DR. LORELL: I would answer no too. I think it
24 still does not address the issue of potential increasing
25 the probability of undertreatment. We were shown no data

1 addressing that.

2 And secondly, I still have a major concern
3 about combining, in a fixed-dose combination, with any
4 other drug an antiplatelet agent.

5 DR. BORER: Susanna?

6 DR. CUNNINGHAM: No, because it doesn't change
7 the issues I'm concerned with.

8 DR. BORER: Mike?

9 DR. ARTMAN: Yes, I would say no as well. I
10 think that again as sort of a clinical pharmacologist, this
11 really goes against one of the principles of rational drug
12 therapy and that is to try and tailor your therapy to each
13 individual patient. And that may change on a month-to-
14 month basis in that given patient.

15 The other issue is related to the compliance
16 issue. For those who have tried to study compliance in
17 populations who are taking a medication that really doesn't
18 make them feel any different, compliance is a very
19 difficult issue. It's very complicated. And the inference
20 is that just because this patient who is taking four or
21 five drugs now will take three or four drugs instead of
22 four or five will have better adherence to their regimen I
23 think is just a lot of hand-waving. There are absolutely
24 no data to support that, and I think this is the wrong way
25 to go.

1 DR. BORER: Tom, you already abstained from
2 number one. Do you want to abstain from two?

3 DR. FLEMING: Yes.

4 DR. BORER: And Blase, you said yes the first
5 time. So, that's not an issue.

6 Steve?

7 DR. NISSEN: No.

8 DR. BORER: Alan? I'm sorry. Alan already
9 said --

10 DR. HIRSCH: I did but I could change my mind
11 if you like.

12 (Laughter.)

13 DR. BORER: No, no.

14 I have a very difficult time with this
15 question. I think that it would be reasonable to approve a
16 combination of these two products as a convenience as long
17 as the uncombined drugs remained available and as long as a
18 range of doses and combinations sufficient to suit my
19 purposes as a prescriber were met.

20 I agree fully with what Bev said. I am
21 concerned about potential problems associated with adding
22 an antiplatelet drug that might not be used appropriately
23 because it's attached to something that the patient may not
24 remember about. But I think I might be able to deal with
25 that or someone might be able to deal with that in certain

1 situations. And the convenience of having that available
2 might outweigh my concern in some situations. What I was
3 not happy about with the drug that was proposed was that it
4 limited my capacity to manipulate cholesterol the way I
5 might choose to do it.

6 So, while I still have the safety concerns that
7 have been raised here, and I agree fully with Mike's
8 comment that I don't think the right way to give drugs is
9 in fixed combinations, that you should titrate individually
10 and be able to change doses individually, nonetheless I
11 think the convenience of having the two pills in one would
12 be reasonable and would be sufficient to outweigh my
13 concerns about safety for approvability as long as my
14 capacity to prescribe the doses I want to prescribe wasn't
15 limited. So, I would vote sort of a tepid yes on this last
16 question.

17 So, I don't think we have to take a big tally
18 on that one. It's not one of the official questions here.

19 DR. TEMPLE: But you did take a tally, didn't
20 you?

21 DR. BORER: Well, we have everybody's answer.
22 Do you want me to summarize it for you? We have 3 yeses, 5
23 noes, and 1 abstain.

24 DR. TEMPLE: It's late to point out what I'm
25 going to point out, and we obviously should have built it

1 into the questions. But you may recall that aspirin is
2 available as an over-the-counter drug and whether people
3 take it and under what circumstances they take it and
4 whether their doctor knows they're taking it is not exactly
5 a known quantity at the present time. I don't know if that
6 makes any difference, and we really didn't mention it. But
7 that seems to have something to do with how much anxiety
8 one should have about someone taking aspirin when he
9 shouldn't. I mean, they already are.

10 DR. BORER: Not to me, for the reasons that
11 Beverly verbalized very well.

12 I think that we've completed our responses.
13 We'll call the meeting adjourned.

14 (Whereupon, at 3:05 p.m., the committee was
15 adjourned.)

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