1 stimulant drugs. We don't know about the
2 cataplectic narcoleptics who weren't. So, I wanted
3 to reflect what we actually looked at, the
4 scientific evidence.
5 DR. KATZ: And, would that be the basis
6 for your no vote as well?
7 DR. SIMPSON: Well, mine is really that
8 they reduced cataplectic events. I guess my
9 understanding of treating it is that they couldn't
10 sort of cure it.
11 DR. PENN: May I just clarify? I didn't
12 mean cure. My motion was not cure, nor did I say
13 monotherapy.
14 DR. KATZ: Right. From the point of view
15 of an effect, you know, that sort of language only
16 being applied to a cure, the vast majority of
17 things we treat and give claims for in indications
18 are for symptomatic, non-curative treatment. So,
19 it is perfectly acceptable for us -- and I think it
20 was implied in Dr. Penn's motion that to vote yes
21 you wouldn't necessarily have to conclude that the
22 drug cures it or wipes these attacks out, but just
23 that there is a decrease in these attacks compared
24 to the control.
25 DR. FALKOWSKI: And you can call it

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1 monotherapy but what the subjects were in these
2 studies were subjects with the condition that were
3 already under medication for this condition. So,
4 to take that leap to say, well, therefore, if you
5 have people with this condition who are not on
6 stimulant drugs, does that follow? I don't believe
7 it does.
8 DR. KATZ: We will take that under
9 advisement.
10 DR. KAWAS: The next question, has the
11 sponsor demonstrated efficacy of Xyrem for the
12 proposed indication to reduce excessive daytime
13 sleepiness in patients with narcolepsy? The floor
14 is open for discussion on this point.
15 At the risk of putting myself back in the
16 same place as last time, I would summarize what we
17 have seen today with regards to excessive daytime
18 sleepiness that there was one study, in a
19 double-blind fashion, that showed subjective
20 changes in sleepiness with the Epworth Scale, and
21 that would be the GHB-2 study. The other study
22 which is being held up as a pivotal study with
23 regards to daytime sleepiness was the Lammers
24 study, which is a small study. Otherwise, I feel
25 that the evidence with regards to daytime

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1 sleepiness was very weak at best, in particular,
2 the only study that proactively made daytime
3 sleepiness the primary outcome measure as well as
4 using objective measures with the MSLT was, in
5 fact, negative. All the other studies were open
6 label. So, here I have a little more --
7 considerably more difficulty actually seeing that
8 the sponsor has demonstrated efficacy for daytime
9 sleepiness. So, what are the committee's thoughts
10 on this? What are the committee's comments on
11 this? Jerry?
12 DR. WOLINSKY: As I tried to point out
13 before, I think this is such an enriched patient
14 population for purposes of the endpoints that were
15 studied, it is hard to know that one could
16 generalize daytime sleepiness effects in a full
17 population of narcoleptics. So, I agree that the
18 data is weak and it is also in a very enriched
19 population.
20 DR. KAWAS: I am not sure I understand.
21 For clarification, enriched with what? You mean
22 enriched for cataplexy?
23 DR. WOLINSKY: Enriched for cataplexy
24 which is not present in all narcoleptics and is not
25 always present at this frequency. So, I don't

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1 think that we would know. I would not know as a
2 clinical that if I had a narcoleptic with sleep
3 attacks or daytime sleepiness but no cataplectic
4 attacks whether I could expect the drug to work or
5 not, and I saw no data to tell me that I could.
6 DR. KAWAS: Any other comments? Any other
7 thoughts before we call the vote on this question?
8 DR. PENN: I move that the company has not
9 provided information to prove that daytime
10 sleepiness is affected by Xyrem, and I would make a
11 comment on my motion, that if the company sees this
12 as an important thing they can do a post-approval
13 study on that specific item and that would be
14 appropriate. I was leaning at the beginning of
15 this to think that there was too much need for full
16 proof on an orphan drug that this might be the case
17 and I was going to give them the benefit of the
18 doubt, but considering the potential for abuse in
19 patients who will say they are just sleepy and the
20 regulatory problems with that, I think we had
21 better be quite strict on this.
22 DR. KAWAS: Can you make that motion
23 without the addendum?
24 DR. PENN: No, no, the addendum is just my
25 comment.

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1 DR. KAWAS: Good. Give me the short
2 motion.
3 DR. PENN: They didn't prove their point.
4 DR. KAWAS: The language is has the
5 sponsor demonstrated efficacy of Xyrem for the
6 proposed indication to treat excessive daytime
7 sleepiness in patients with narcolepsy? So, a vote
8 of yes the way I just worded it would suggest that
9 the company has shown efficacy, similar to the last
10 vote. A vote of no would suggest that the company
11 has not shown efficacy for that particular
12 indication. So, all in favor of yes, the company
13 has shown efficacy for the indication of daytime
14 sleepiness, please raise your hand.
15 [No show of hands]
16 All if favor of no?
17 [Show of hands]
18 Let the record show that it was unanimous.
19 It might be the only time today.
20 DR. TITUS: And enter nine names please
21 into the record.
22 [Drs. Penix, Van Belle, Penn, Kawas,
23 Wolinsky, Roman, Falkowski, Simpson and Lacey voted
24 against the motion]
25 DR. KAWAS: Now, the second question that

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