

1 The Watch PAT device is a finger-mounted optic  
2 pneumatic sensor. It actually detects obstructive  
3 events from the sympathetic events that are caused by  
4 the obstruction. There has been some promising  
5 correlation with full polysomnography and then another  
6 device.

7 Then let me just give full disclosure. I  
8 have no financial interest in the company that makes  
9 SleepStrip, but I am about to start a study looking at  
10 this as a screening device. So this is an upper lip  
11 adhesive device that has flow sensors and oximetry  
12 and, again, some promising early data that we are  
13 going to try and evaluate.

14 So issue number one was an easy one for  
15 me: the standard of care for diagnosis of sleep  
16 apnea. It's polysomnography. I am quite certain that  
17 Dr. Epstein and his colleagues would agree with that  
18 from the sleep medicine world.

19 The second issue was the possibility of  
20 patients self-diagnosing sleep apnea. First of all --  
21 and this would be related to the signs and symptoms of  
22 sleep apnea. So let's make sure we know what those

1 are. Snoring, excessive daytime somnolence, and  
2 witnessed apneas are the three mainstays. There are  
3 a number of other symptoms that patients can present  
4 with, including morning headaches, irritability,  
5 neurocognitive deficits, including memory impairments,  
6 impotence, and nocturia, particularly in children.

7 In addition to those signs and symptoms,  
8 there are other so-called risk factors for developing  
9 sleep apnea, so advancing age, gender. Being male is  
10 not a good thing. Body mass index. So that's the  
11 weight of the patient and then neck circumference. So  
12 we know that these are associated with the development  
13 of sleep apnea.

14 So looking individually at the three  
15 primary symptoms, snoring to start with, there is  
16 quite a strong correlation of snoring with sleep  
17 apnea, but you can see it's as low as 72 percent, as  
18 high as 87 percent in a number of studies that have  
19 looked at this as a specific symptom of sleep apnea.

20 Probably the best way for evaluating  
21 excessive daytime somnolence in an easy fashion is the  
22 Epworth Sleepiness Scale. It's the most commonly

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1 utilized tool for assessing sleepiness. But even  
2 this, 41 percent only of 440 snorers with an elevated  
3 Epworth scale score have sleep apnea, 61 percent in  
4 another study, so, again, not a very good predictor of  
5 the likelihood of having sleep apnea.

6 What about witnessed apneas, which is  
7 another common finding more commonly seen in patients  
8 with sleep apnea but, again, not a one-to-one  
9 correlation? So armed with some of this information,  
10 a number of investigators have attempted to develop  
11 models for predicting sleep apnea, again based on  
12 either symptoms and/or some of the other risk factors  
13 that I mentioned.

14 This was one study of 410 patients with a  
15 relatively complex algorithm. And you can see only a  
16 46 percent positive predictive value in diagnosing  
17 sleep apnea.

18 Another study with slightly better data,  
19 427 patients, again, acknowledging snoring, witnessed  
20 apneas, gasping, age, gender, BMI, found only a 60  
21 percent sensitivity in diagnosing sleep apnea.

22 And then the larger study of 744 patients,

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1 somewhat better results, a more complex scoring  
2 system, but you can see 86 percent sensitivity, 77  
3 percent specificity, 89 percent positive predictive  
4 value.

5 So based on this evidence-based review, I  
6 would say one cannot reliably predict the presence of  
7 sleep apnea without performing some type of  
8 polysomnography.

9 And then the final issue is, again, a  
10 related issue. Can we determine the effectiveness of  
11 treatment by evaluating signs and symptoms of sleep  
12 apnea? I'm just going to show three of many studies  
13 that would suggest that that we can't do that.

14 So this was an earlier study from Shiro  
15 Fujita, who did a lot of the early work with surgical  
16 interventions with sleep apnea. This was on  
17 palatopharyngoplasty. He was one of the first to  
18 recognize that even in his group of 31 patients, even  
19 patients who had improvement in their sleepiness may  
20 not have improvement in their polysomnographic  
21 evidence of sleep apnea, so creating what was referred  
22 to earlier as the so-called silent sleep apneic.

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1 Nelson Powell in Palo Alto has done a lot  
2 of work with radiofrequency ablation of the palates.  
3 In this study of 22 patients, they showed no change in  
4 the polysomnographic parameters in their patients, but  
5 the snoring improved by 77 percent and the sleepiness  
6 improved in 39 percent. So, again, the patients are  
7 going to feel better, but they may not be better.

8 And then our own data looking at hyoid  
9 myotomy, genioglossus advancement, and palatal frontal  
10 plasty, 32 patients, again, we have very good  
11 improvement in the sleep but not as good as we got in  
12 the snoring and the sleepiness. So that's one reason  
13 why these patients do need to be followed up  
14 post-surgically and reevaluated with polysomnography  
15 after any surgical intervention.

16 So, to finish off, improvements in the  
17 signs and symptoms of sleep apnea often occur in the  
18 absence of objective evidence of improvement in sleep  
19 apnea.

20 Thank you.

21 CHAIRPERSON GULYA: Thank you very much,  
22 Dr. Terris.

1 Do any of the panelists have questions for  
2 Dr. Terris? I think we will have an opportunity to  
3 readdress some of these issues when we go into our  
4 deliberations over the questions as well. Yes?

5 DR. ROSENTHAL: Dr. Terris?

6 CHAIRPERSON GULYA: Could you please give  
7 your name?

8 DR. ROSENTHAL: Rosenthal, Division  
9 Director. That was an excellent presentation. Can  
10 you tell us something about the longitudinal nature of  
11 this condition? Do people progress from mild to  
12 moderate to severe over time?

13 DR. TERRIS: Yes, it gets worse over time  
14 for a lot of different reasons, primarily related to  
15 increasing weight and laxity of tissue. So it's one  
16 of those progressive diseases, chronic diseases, over  
17 time.

18 CHAIRPERSON GULYA: Yes?

19 MEMBER ZUNIGA: John Zuniga. Related to  
20 that same question, is there a percentage of patients  
21 that go from mild to severe and vice versa without  
22 treatment?

1 DR. TERRIS: I'm not aware of a single  
2 patient that went from severe to mild without  
3 treatment depending on how you define treatment. I  
4 just saw a patient in the office the other day who had  
5 a gastric bypass, which I consider treatment for sleep  
6 apnea, and lost a couple of hundred pounds and went  
7 from an RDI of 90 to an RDI of 3. So if you include  
8 that as treatment, then no, I have never heard of that  
9 ever happening. But to go from mild disease to severe  
10 disease, yes, it happens with regularity.

11 CHAIRPERSON GULYA: Yes, Dr. Woodson?

12 DR. WOODSON: Gayle Woodson. Now, you  
13 have patients who say they feel better but are not  
14 better. If you have someone who does feel better and  
15 he's functioning better, then there's a disconnect  
16 between the functional results of it and the  
17 objective.

18 Now, have you looked at like sleep onset  
19 time because that is one objective measure of whether  
20 or not they're really less sleepy, rather than just  
21 saying they're less sleepy because they don't want  
22 another operation?

1 DR. TERRIS: Yes. Well, the problem is  
2 it's not --

3 CHAIRPERSON GULYA: Please identify  
4 yourself for the transcriptionist. They're trying to  
5 --

6 DR. TERRIS: That was Gayle Woodson. I'm  
7 Dave Terris.

8 EXECUTIVE SECRETARY S. THORNTON: Yes. I  
9 think once around for everybody clearly into the  
10 microphone will be enough for the transcriptionist.  
11 Correct?

12 CHAIRPERSON GULYA: Okay.

13 EXECUTIVE SECRETARY S. THORNTON: Thank  
14 you.

15 DR. TERRIS: The problem is that it's kind  
16 of like hypertension or diabetes. I mean, if you ask  
17 a patient with hypertension, "Do you feel badly," they  
18 say, "No. I feel fine." But, nevertheless, this is  
19 a chronic disease that is taking its -- exacting its  
20 toll over years. So to me, yes, there are better ways  
21 or good ways to carefully document if the sleepiness  
22 has gotten better.

1           On the other hand, even if the sleepiness  
2           is better, they can still have the cardiovascular  
3           ramifications of the obstructive events occurring  
4           frequently during the night.

5           DR. WOODSON: Yes. But isn't the evidence  
6           for the cardiovascular kind of epidemiologic and a lot  
7           of it is snorers have more strokes? There's not that  
8           much good prospective data about people documented to  
9           having sleep apnea and the results.

10           So specifically somebody who objectively  
11           in a lot of ways is not better. Is there a  
12           possibility he might not be having as much sequelae?  
13           I mean, we don't have the data to say that, really.  
14           I mean, it just makes sense compared to hypertension,  
15           but we don't really have that data, right?

16           DR. TERRIS: I'm trying to think if that  
17           specific study has been done. And if anybody else on  
18           the panel is aware of it, please speak out.

19           DR. LI: Kasey Li from Stanford. I just  
20           want to make a couple of comments. One, the  
21           improvement that you see in some of these studies,  
22           none of them are from placebo-controlled. So they're

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1 short-term studies.

2 So, one, you have to look at the  
3 possibility of placebo effect on improvement of  
4 symptoms. That's number one. Number two, a lot of  
5 times you see short-term improvement in a matter of  
6 three to six months in terms of functional  
7 improvement. They have relapse. And even though they  
8 may have some improvement, that doesn't mean that they  
9 have resolution of the disease. So the improvement in  
10 snoring doesn't really reflect, as you see in the  
11 literature, an improvement or resolution of sleep  
12 apnea.

13 There are a lot of epidemiology studies,  
14 two large studies from Wisconsin Cohort as well as the  
15 National Heart Lung study looking at specifically and  
16 demonstrating that sleep apnea is an independent risk  
17 factor, I think, for cardiovascular disease.

18 So I think that the evidence is fairly  
19 profound sleep apnea by itself significant affects the  
20 well-being of the patient.

21 CHAIRPERSON GULYA: Thank you, Dr. Li.

22 Okay.

1 DR. TERRIS: I certainly would agree with  
2 all of those comments. I guess it still doesn't get  
3 at Gail's question of if the patient feels better and  
4 their sleepiness is better, even if they have  
5 polysomnographic evidence of sleep apnea, is their  
6 risk of cardiovascular disease diminished?

7 Again, I don't know whether that study has  
8 been done, but I can't imagine that that would be the  
9 case. That's the only way. I would say that.

10 CHAIRPERSON GULYA: Okay. Well, thank you  
11 very much. We will now hear from Dr. Demko.

12 DR. DEMKO: Thank you.

13 My name is Gail Demko. I am a dentist in  
14 private practice. And my practice has been limited to  
15 treatment of patients with obstructive sleep apnea  
16 since 1997. What I am going to talk about today is  
17 oral appliance side effects and how I use that in  
18 patient selection, appliance selection because there  
19 is no question about it. Of all of the patients that  
20 are referred to me, I treat fewer than 75 percent of  
21 them. And I am going to go fast.

22 What I want you to worry about is what

1 everybody else has been talking about, symptom  
2 responders. This is from Anette Fransson's Ph.D.  
3 thesis in Sweden, where patients who are given oral  
4 appliances and were subjectively better when tested  
5 polysomnographically, it was found out that they were  
6 not better. So even though the patients felt fine,  
7 they weren't.

8           The majority of the appliances on the  
9 market are mandibular repositioning devices. Their  
10 job is to bring the jaw forward and keep it closed.  
11 Those two movements open the airway, both  
12 retroglossally and behind the soft palate.

13           What I worry about is the more you open  
14 that mandible, the more it is going to be in a  
15 rotational mode. The more it rotates where the  
16 genioglossus attaches at the anterior portion of the  
17 mandible, the more it is going to rotate backwards and  
18 close the airway.

19           So one of the things in choosing an  
20 appliance, one has to look at how much do you have to  
21 open that patient to get an effect? This is a typical  
22 ceph on a patient of mine with and without an oral

1 appliance. The more you open him, the more you are  
2 going to have to bring him forward, which is basically  
3 what this person is saying.

4 So there are short-term changes with  
5 appliance use. There are long-term changes.  
6 Short-term many times is just self-resolving. The  
7 excessive salivation occurs when a patient can close  
8 around an appliance because it is small enough.

9 Other patients will complain of dry mouth  
10 because they cannot close. But the bulk of the  
11 appliance is so big that they have lip incompetency  
12 and now are mouth breathing, which is basically what  
13 I don't want a patient to do because nasal breathing  
14 makes the appliance work better.

15 Pain in individual teeth happens almost  
16 always in patients who have teeth with very sharp  
17 edges, very crooked teeth. It can be that the model  
18 that I sent to the laboratory was worn in shipping,  
19 the impression was distorted, or that when the patient  
20 took a boil and bite appliance home, if they got them  
21 over the Web, which they can illegally from England  
22 and Canada, that if there is contact with the edge of

1 that tooth and the hard outer shell of the boil and  
2 bite, there will be pain. Very simple. Adjust the  
3 appliance.

4 Pain in the anterior teeth that the  
5 patient is clenching, clenching forces can often  
6 intrude teeth. Again, I want to make sure that that  
7 patient has contact all the way around on the arch, at  
8 least in a tripod configuration.

9 The mobility of the anterior teeth is  
10 extremely common from the forces of the mandible being  
11 forward by virtue of the appliance pulling it forward,  
12 the muscles pulling it back. I will always go in and  
13 adjust an appliance on the facial aspect of the upper  
14 anteriors and the lingual aspect of the mandibular and  
15 take those forces off the teeth. It doesn't stop them  
16 from moving, but it stops them from being mobile.

17 Posterior open bite in the morning. There  
18 are always arguments about why this happens, but  
19 Fernanda de Almeida has done MRI studies where as that  
20 mandible is moved down and forward out of the socket,  
21 you actually will get edema in the joint space. Some  
22 theorize it's shortening of the internal lateral

1 pterygoid, but that couldn't happen as quickly as this  
2 fluid buildup is. And within two to three weeks,  
3 patients will have evidence of a posterior open bite,  
4 where their anterior teeth are the only things that  
5 contact because the fluid is holding the condyle down  
6 and forward.

7 I have patients who will chew bubble gum,  
8 just clench, but I tell them that that fluid needs to  
9 be gone in 15 minutes after they get up in the morning  
10 or there are going to be problems later on. It  
11 doesn't prevent problems later on, but it seems to  
12 minimize them.

13 Patients who have joint pain bilaterally  
14 I find that predominantly it is excessive mandibular  
15 advancement, which for some patients may be anything,  
16 but it's beyond the ability of the joint structures to  
17 tolerate. In some cases just setting the appliance  
18 back further is fine and takes care of the problem.  
19 In some places, they will have to discontinue care.

20 If they have unilateral pain, it seems  
21 more often it is an eccentricity so that the mandible  
22 is off to one side. Once you line up their midlines

1 or however they are naturally because patients can  
2 deviate as they open and close their mandible, you  
3 want to match that movement with your appliance, that  
4 just moving the appliance one way or the other will  
5 solve that problem.

6 There are allergic reactions, people who  
7 are nickel-allergic, latex-allergic, and methyl  
8 methacrylate. All three of those things are in  
9 various appliances, and patients do need to be warned  
10 about that.

11 Things that worry me: long-term changes.  
12 These long-term changes do not normally become obvious  
13 for a year. Anything that happens within six months  
14 of wearing an appliance seems to be self-resolving if  
15 the appliance use is discontinued. After that, all  
16 bets are off. These changes are permanent.

17 So in this case, I have gotten patients  
18 who have developed all sorts of fibromas from hitting  
19 the edges of appliances. What I did with this, the  
20 patient had to go to the oral surgeon, have the  
21 fibromas removed. We redesigned the appliance so  
22 there was no more irritation of soft tissues.

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1 Hard tissues changes are related to  
2 incomplete coverage of the dental arch -- we argue  
3 about this at all meetings -- and related pressures on  
4 the dental arch because these appliances are basically  
5 functional orthodontic appliances. The big deal is  
6 that transseptal fibers, which sit in the roots around  
7 the teeth, are the fibers that kick off orthodontic  
8 movement.

9 And once they are activated, they transmit  
10 forces around the arch, even away from where the force  
11 is originally brought. And they will continue to act  
12 24 hours a day with or without forces being brought.

13 So you will have with incomplete coverage  
14 block movement of teeth. So this is just showing that  
15 I could take a model where the floss could go between  
16 those last two teeth. Open contacts are fairly small  
17 in most instances, solve that by redesigning the  
18 appliance or changing it to make sure that the back  
19 molars are hooked around to now when you move the  
20 teeth, you move all of them, as opposed to leaving two  
21 behind.

22 We know that there is anterior tooth

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1 movement. Rich's article, Rose's article, Marklund's  
2 article, all of them will tell you anterior tooth  
3 movement. The forces brought on those teeth take the  
4 maxillary teeth, make them more upright, take the  
5 mandibular teeth, and actually move them towards the  
6 lip.

7           What I will see over periods of time is  
8 opening interdental spaces. And this is a combination  
9 of effect, but it is from those transseptal fibers.  
10 The only way to put these patients back where they  
11 started if that's possible would be orthodontics.  
12 However, with so many of these, the posterior teeth  
13 extrude into position. And now they are locked  
14 forever in that bite.

15           Again, the fluid build-up is a short-term  
16 change that can lead to long-term changes because as  
17 the condyle is held out of the fossa, the space that  
18 that creates, the posterior teeth will extrude and  
19 either keep it so the patient -- this is a physician.  
20 He is so happy with this appliance, he refuses to give  
21 it up.

22           Again, I don't see this type of movement

1 as often as other people do because I am really riding  
2 patients hard. He has had spacing in his teeth. He  
3 has had advanced modal, almost a quarter of an inch,  
4 in his mouth.

5 This is a patient that used to be an  
6 anterior grinder and wear his teeth. And now he can't  
7 even touch his front teeth anymore. This is a patient  
8 who was wearing an appliance, had mandibular  
9 advancement. They put her in orthodontics. She had  
10 a bridge on the upper that wouldn't move. They put a  
11 lingual wire on the bottom so those teeth wouldn't  
12 move. And after her orthodontics, she had a lovely  
13 anterior open bite.

14 So there is a disagreement now among us as  
15 to do materials of the appliance, do thermal active  
16 acrylic appliances, Klearway, PM Positioner, or others  
17 that you will heat up every night to put them in, move  
18 teeth more than hard acrylics? There is no published  
19 data that appears definitive on that.

20 Does moving the patient's mandible forward  
21 seem to matter? Big deal. The statistical studies  
22 show us that 75 percent advancement within the

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1 patient's individual physiologic range seems to be the  
2 most effective position. However, that really means  
3 as statistics look only at large groups, that my  
4 patients have been successful anywhere between moving  
5 them 50 to 125 percent of their normal range.

6 So statistics tell us anybody who can't  
7 move his jaw six millimeters, an appliance is not  
8 going to be effective that moves the jaw forward. And  
9 patients' ranges will vary from 4 to 18 millimeters.  
10 The further you move them, the more likely there are  
11 side effects.

12 Chris Robertson is looking at statistics  
13 again, not individual cases, on how many patients  
14 move. The permanent movement of teeth begins between  
15 6 and 12 months, and it continues past 30. He's up  
16 now to two more years of data. It is not published.  
17 He keeps the same original cohort and crunches  
18 different things and publishes lots of articles.

19 This is a patient who bought her appliance  
20 online from overseas. The same thing happens to these  
21 boil and bite appliances as happens with the  
22 prescription appliances that in this country are

1 available from dentists.

2           What I don't like to see is anything that  
3 does not completely cover the mandibular teeth  
4 completely. When you have these lingual flanges, the  
5 forces on those lower anterior teeth will actually  
6 avulse the teeth, even if they were healthy to start  
7 with.

8           What you want to be aware of is that there  
9 is a significant decrease measured in the overjet and  
10 overbite. And in a Pantin study, only two of nine  
11 patients who had total lack of contact on their  
12 posterior teeth even noticed this. Again, in Pantin,  
13 fewer than half of his patients with occlusal changes  
14 were aware that their teeth didn't hit like they used  
15 to because these changes are so subtle.

16           Tongue retaining devices are also on the  
17 market. There are very few of them. They are not  
18 without problems. The majority of practitioners don't  
19 use them because they're relatively tricky and  
20 difficult to spit, but that will change as people come  
21 up with better ideas and better mousetraps.

22           A tongue retaining device that was

1 explained earlier moves the tongue bodily forward and  
2 forces nasal breathing in most cases. That is not  
3 true with some of the other designs. They are less  
4 effective than mandibular repositioners. And all  
5 studies done on their efficacy back in the 1980s with  
6 Ros Cartwright looked at also changing weight and  
7 position of sleep. Therefore, they never studied the  
8 TRD all by itself, nor did they break those out.

9 Again, short-term side effects and  
10 long-term side effects. It's going to cause excessive  
11 salivation, irritation on the tip of the tongue from  
12 the suction. Simple. You teach the patient not to  
13 put quite so much suction on the tip of their tongue.  
14 Irritation from the edge of the appliance, wherever it  
15 hits in the mouth, if it hits the Stenson's duct,  
16 where patients have salivary flow or down in the  
17 underneath of their tongue, you're going to get scar  
18 buildup, that appliance needs to be reshaped or  
19 replaced.

20 Tongue lengthening. People never thought  
21 of this. I only picked it up because one of my  
22 patients is Hispanic and she is a Spanish teacher.

1 After three years of using her tongue retaining  
2 device, she could no longer speak Spanish. She  
3 couldn't roll her R's. She had to go into speech  
4 therapy for two months to be able to go back to work.  
5 She's still wearing her tongue retaining device, and  
6 it's three times even longer than that. Now it's got  
7 52 millimeters. But with speech therapy, she can take  
8 care of that.

9 So if you put suction on soft tissue, it's  
10 going to move. Her teeth have also extruded in the  
11 past because the position that these appliances keep  
12 the anterior teeth open, it means that if there is not  
13 complete coverage of those teeth in back holding them  
14 in position, they are going to move.

15 Every patient of mine who goes into a  
16 tongue retaining device for more than six weeks  
17 because it takes at least that long before they can  
18 even learn to tolerate it gets retainers. And since  
19 this patient has been in retainers, the last two years  
20 her teeth have not moved, but her bite is still  
21 permanently there. It is probably that that change  
22 came from the fluid buildup in the joint because once

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1 you move the patient, open the anderum sizably, more  
2 than a centimeter, there is going to be fluid buildup  
3 in the joint.

4 So how do I use all of this to help me  
5 decide what patient I am going to treat and what  
6 appliance. I am going to do the typical looking at  
7 decayed, missing, and filled. Do I have enough teeth  
8 to hold onto the appliance? The forces these  
9 appliances put on teeth are phenomenal and their  
10 periodontal status. I don't want to be doing  
11 extractions. That is a job for an oral surgeon. That  
12 is basically straightforward dental evaluation.

13 This is the evaluation that really makes  
14 a difference as to how I am going to choose oral  
15 appliance choice. When I am going to look, I am going  
16 to look at the oropharyngeal opening. Is it wide  
17 open? I want that patient. Is it looking like this?  
18 I want them to go see a surgeon first. If it looks  
19 like this, they're getting a tongue retaining device  
20 because I can't see anything back there. I may as  
21 well get that tongue that's as big as Cleveland out of  
22 the way. If I see this, I am going to make sure that

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1 that is not consistently what they are doing before I  
2 send them back to their physician.

3 When I look at their anterior open bite,  
4 I want to know how these teeth are because the more I  
5 open that anterior segment, the more likely it is that  
6 I am going to rotate that condyle out of the fossal.

7 If their bite is like this, I have to open  
8 them 11 millimeters to get them past their front teeth  
9 in the first place. Then I have to have room for the  
10 appliance or I'm going to be rotating that condyle way  
11 out of the fossal, and I'm going to end up with a  
12 little bit more problem.

13 The catch is with the anterior open bites,  
14 those patients, every time you put a millimeter of  
15 material between their molars, it corresponds to a  
16 three-millimeter opening in the anterior. So if I am  
17 putting in a boil and bite appliance on that patient  
18 that is going to open the posterior six millimeters,  
19 I'm going to be opening them about 18 in front, going  
20 to get into a lot of trouble. So, again, I need to  
21 know where their teeth are because I can decide which  
22 appliance I am going to use.

1 I want to look at tooth damage. This  
2 patient is a severe gastroesophageal reflex patient  
3 because of his sleep apnea, lo and behold. And when  
4 he is sleeping at night, that acid comes up in his  
5 mouth, eats his teeth away. And his teeth are so  
6 short, the appliance doesn't hold on. He's in a  
7 tongue retaining device at this point.

8 This patient was sent right off to the  
9 maxillofacial surgeon because I wasn't going to put an  
10 appliance in a mouth that looked like that when she is  
11 in the full bite. This patient is a severe bruxer.  
12 He's been eating his teeth away for years. He breaks  
13 his appliance routinely, about on a monthly basis. I  
14 finally taught him how to realign his own tap in this  
15 case, and he has been happy ever since.

16 This patient has periodontal problems,  
17 missing teeth. Put that patient in a tongue  
18 stabilizer.

19 Patients I don't touch. I don't touch  
20 this patient. This is a hypoplastic maxilla. I am  
21 moving the mandible forward against the maxilla as my  
22 anchor. If the maxilla is too far back, it doesn't

1 matter how far I move that mandible. It's not going  
2 to be far enough. Don't treat steep mandibular jaws.

3 This patient up here doesn't look it  
4 because she doesn't have your typical long lower face.  
5 She has a 50-degree angle on her mandible. So that  
6 any appliance I put in her mouth will automatically  
7 rotate her mandible almost directly back. And I will  
8 simply lower and exacerbate her blockage.

9 Patients that are in cross-bite, either  
10 unilateral or bilateral, where I've got a jaw size  
11 discrepancy, I will do my best to bring those patients  
12 forward, but it would be really nice if their palates  
13 could be split because if the palate is narrow, the  
14 nasal passages are narrow, and I really like to have  
15 free nasal breathing with my appliances.

16 So for a mandibular repositioning device,  
17 I want to treat retrognathic patients. If they come  
18 in looking like Prince Charles with his money, that  
19 would be nice. Thin patients, young patients. The  
20 older the patient is, you get over 65, appliances  
21 don't work as well. When you're sagging on the  
22 outside, you're sagging on the inside. It's really

1 hard to get the appliances to work.

2 Female patients, Marklund, new study shows  
3 an odds ratio of over 12 for just being female with  
4 the success of an oral appliance. I want a healthy  
5 dentition. I want a protrusive range of more than  
6 seven millimeters. And I would like to have a  
7 moderate anterior overbite, which their teeth do  
8 overlap.

9 With a tongue retaining device, again, the  
10 correlates with success are normal weight, that they  
11 are worse in a supine position, -- therefore, they get  
12 better if you put them in a lateral position --  
13 macroglossia, definitely not tongue-tied, and normal  
14 soft palate length.

15 Going to fail with obesity. Retrognathic  
16 patients do not do well with tongue retaining devices  
17 because the real problem is jaw size, short lingual  
18 frenum, tongue-tied, severe sleep apnea, no positional  
19 changes. And, no matter what, it's less effective  
20 than a mandibular repositioner.

21 So selection of the appliance depends on  
22 the patient's dental health, on their jaw size, the

1 severity of disease, age, and lifestyle because I'm  
2 not going to give somebody an appliance that looks  
3 really clunky if that person is really worried about  
4 his Saturday night date.

5 Looking at occlusal schemes, I am looking  
6 at their bruxism and whether they have acid reflex.  
7 TMJ history, it turns out I have very little problem  
8 with patients who have a history of TMJ. I always  
9 give it to people who have never had it before. The  
10 people who had it before seem to get better.  
11 Mandibular repositioners are one of the number one  
12 appliances used for treating locked jaws.

13 So fabrication requires that I measure how  
14 much advancement can I get with a George gauge. I  
15 like using adjustable appliances to limit the amount  
16 of joint problems I am going to have. If I take an  
17 impression, I always worry about aspiration of that  
18 material. I want complete coverage of the dentition  
19 and have an impression that doesn't distort, doesn't  
20 have bubbles, or voids. With a tongue retaining  
21 device, I'll do anything to prevent tooth extrusion.

22 George gauges are fitted in the mouth,

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1 like this, so the teeth come all the way together.  
2 They do have a bite for top and bottom. The patient  
3 can pull his mandible all the way back without tooth  
4 contact, push it all the way out. And on this handle,  
5 here is a millimeter scale that will give you about 18  
6 vectors of movement all put into one nice little  
7 package. It's not as accurate as we would like, but  
8 it's great. It's all we've got.

9 And then a bite registration is taken at  
10 the position where I think they are not going to get  
11 TMJ pain, which is if they come in with preexisting  
12 TMJ problems, I put them 50 percent forward.  
13 Otherwise it's 60 percent.

14 So when patients are treating themselves,  
15 first of all, they're not going to have an idea what  
16 kind of periodontal condition that they have because  
17 they don't go to the dentist anyway when they have got  
18 problems. And now with all of this big push on  
19 periodontal disease causing heart disease, you don't  
20 see a huge influx of patients into the office saying,  
21 "Stop my heart disease. I need my gums cleaned."

22 You have all of the parafunctions that

1 patients are not aware of. Clenching really bugs me  
2 more than anything else. Bruxism you can see.  
3 Clenching is strictly by report. I look at the  
4 occlusal clasp, the proper fit of the appliance, their  
5 denial of side effects, just as they deny they have  
6 obstructive sleep apnea. All appliances do the same  
7 thing. There has never been any study that shows that  
8 one is less damaging than any others. It is  
9 unpredictable who is going to have problems with tooth  
10 movement when and how far.

11 One thing we have noticed is that  
12 pregnancy makes it worse, that I've had patients where  
13 there was no jaw repositioning, no tooth movement, and  
14 they got pregnant. When joints start letting go, they  
15 let go. And within two months, she had moved over a  
16 quarter inch.

17 So, in conclusion, there is no way to  
18 predict who will be successful with oral appliances.  
19 Statistics run just about 62 percent of unselected  
20 patients who are successful patients who get worse are  
21 the ones with steep mandibular angles, patients who  
22 gain weight during study times.

1 We can't predict all of the people who  
2 actually do get worse. There is no way to predict who  
3 will have unwanted side effects. Patients are not  
4 aware of these dental changes. The patients with  
5 symptom relief may still have serious disease. And  
6 there are very few diseases maintaining written  
7 publishable data banks. Alan Lowe does because he is  
8 university-based. He says 75 percent of his patients  
9 have dental changes at 5 years.

10 Glenn Clark used to be at UCLA, is now at  
11 USC. He says 50 percent at 5 years. However, Alan's  
12 work is clinical. He actually sees the patient. This  
13 was by questionnaire. So knowing that patients don't  
14 notice that they have dental changes, it could be very  
15 high.

16 Christ Robertson did not look at the  
17 number. He simply looked at overall statistics. And  
18 Marie Marklund is starting putting together all of her  
19 5-year data now on over 800 patients.

20 Any questions?

21 CHAIRPERSON GULYA: Thank you very much.

22 Do any of the panelists have any questions? Yes?

1 DR. STERN: While I understand that there  
2 are a lot of dental changes, how serious are these  
3 dental changes as far as the repercussions other than  
4 cosmetic repercussion, as in facial appearance doesn't  
5 look so good and the bite is not so good? How serious  
6 would that be to the patient if they come in and they  
7 have these changes? Does it really affect them other  
8 than, you know, appearance-wise?

9 DR. DEMKO: Right. Basically what I look  
10 for with patients is the patient I showed you with the  
11 great morbidity, where his mandible came forward, he  
12 is a physician. When he disappeared, wore his  
13 appliance, kind of jerry-rigged it himself for five  
14 years, when he came back and he looked like this and  
15 I really went through the ceiling because dentists  
16 worry in microns, not in millimeters, he looked at me,  
17 and he said, "I'm a physician. The side effects of  
18 what I do kill patients. All you did was move my  
19 jaw." For him, who was a severe sleep apneic and it  
20 totally controlled his disease, he was willing to put  
21 up with that.

22 What I try to do with patients is the

1 minute I see something changing where I think it's  
2 going to be permanent, I sit down and talk to the  
3 patient and try to get them to go back on CPAP. If  
4 they refuse, then I always send a letter to their  
5 dentist saying that "This patient's occlusion is  
6 changing." I have never had a patient complain of  
7 anything other than cosmetic changes. They don't have  
8 any difficulty with function. They manage just fine,  
9 just as do edentulous patients who don't wear  
10 dentures.

11 CHAIRPERSON GULYA: Okay. Dr. Suzuki?

12 MEMBER SUZUKI: Jon Suzuki, Dental. Have  
13 you ever had to resort to either major or minor  
14 occlusal adjustment involving enamoplasty when the  
15 teeth migrate or super-erupt? You didn't mention  
16 that.

17 DR. DEMKO: I actually send them back to  
18 their own dentist. Because all I do is sleep  
19 dentistry, I don't want any general dentist thinking  
20 that I am stepping on his toes. So I will send them  
21 back, explaining what I think should be done. But I  
22 don't do that. I will send them to the orthodontist.

1 I will send them back to a general dentist.

2 But yes, enamoplasty is very important,  
3 especially when you have got a super eruption, mild  
4 super eruption, of molars. That's what's locking them  
5 in place if I can get rid of that.

6 One of the things I do with oral  
7 appliances is when the anterior teeth start moving,  
8 you can actually put dots of acrylic. Maxillary teeth  
9 tend to labiovert. Mandibular teeth lingualize. You  
10 can put dots of plastic and push the teeth back into  
11 position using an appliance that is thick enough, you  
12 can use it as an orthodontic appliance, put the teeth  
13 back. You just can't if they start splitting out.

14 CHAIRPERSON GULYA: Okay. Dr. Terris?

15 DR. TERRIS: Gail, I enjoyed your  
16 presentation. It was very informative. One thing I  
17 hope you can clarify for me, I would have thought that  
18 in terms of the safety of the appliances, one could  
19 make the argument, "Well, the patient can self-treat."  
20 And if they're having some of these problems, they can  
21 just stop or seek help.

22 It sounded like from what you said that

1 some of the changes that can start while they're  
2 self-treating can become permanent essentially. Is  
3 that true?

4 DR. DEMKO: Right. It's between 6 and 12  
5 months is where we start seeing changes that will  
6 become permanent.

7 DR. TERRIS: Thanks. Okay.

8 CHAIRPERSON GULYA: Dr. Zuniga?

9 MEMBER ZUNIGA: John Zuniga. Do you have  
10 any MRI data to collaborate or support the theory that  
11 there is, in fact, edema in the temporomandibular  
12 joint?

13 DR. DEMKO: The only study done was  
14 published by Fernanda de Almeida. That was published  
15 two years ago. She looked at only eight patients.  
16 They were looking at how far out of the fossa was the  
17 appliance moving them related to the kind of pain and  
18 compliance of that patient. She did pick up that  
19 there was some proliferation of posterior fibers.  
20 There was definite edema. But that was the only  
21 change they picked up.

22 There are no studies that I know of done

1 long-term, certainly not published, looking at MRI  
2 data as to whether we get changes, permanent changes,  
3 in the socket, in the joint.

4 CHAIRPERSON GULYA: All right. Dr. Li?

5 DR. LI: Gail, a couple of issues. One,  
6 can you comment on the difference in terms of  
7 retention of the appliance between the boil and bite  
8 type versus a custom type? That's the first question.  
9 The second question is in terms of objective testing  
10 after the delivery of the appliance and on follow-up?

11 DR. DEMKO: Okay. The boil and bites are  
12 very rarely as retentive as the custom fabricated  
13 because the custom fabricated locks into better  
14 positioning. Boil and bites when they're heated up,  
15 you bite down into them. They don't come back in and  
16 hug the neck of the tooth. So you're not going to  
17 have a lot of undercut and retention there.

18 The other appliances, then they're custom  
19 fabricated. You can put clips on them, clasps. You  
20 have other ways of making additional retention on  
21 those. And there's a lot that even I get back from  
22 the laboratory and have to paint on more plastic to

1 lock in, especially on bruxors or people who have lost  
2 over 20 percent of their tooth bite. So that  
3 retention is very different between boil and bites and  
4 the custom fabricated.

5 As for objective testing, I will do  
6 preliminary testing using something like a SleepStrip  
7 or an oximeter on a patient to make sure that the  
8 appliance is titrated out to where that says  
9 everything is fine. Then they go back for full  
10 polysome because it's hard to try and get patients to  
11 do that. They don't want to go through another sleep  
12 study.

13 I will not give them the results of the  
14 test for my Better SleepStrip or whatever, but  
15 routinely I'm finding that they're not far enough  
16 forward. I just had a patient come back with a  
17 SleepStrip of 3, which means he's having more than 25  
18 events an hour. If anything, that is probably under  
19 recording. I want that patient to move his appliance  
20 further forward and go back for full polysome.

21 CHAIRPERSON GULYA: I think this will be  
22 the last question before we start deliberating.

1 MEMBER ZUNIGA: Thank you. John Zuniga  
2 once again. What is the cost difference between the  
3 boil and bite and the hard acrylic process?

4 DR. DEMKO: Do you mean my cost or --

5 MEMBER ZUNIGA: General.

6 DR. DEMKO: -- or the patient is going to  
7 be doing this? The lab fees run up to, maximum is,  
8 \$600 that I have seen for lab fees. That is for the  
9 silencer, the boil and bites. They can get them from  
10 England for \$30.

11 MEMBER ZUNIGA: And the patient who cannot  
12 afford the larger cost, will you use the boil and  
13 bite? Do you have any personal outcomes that you can  
14 share with us?

15 DR. DEMKO: I very rarely use boil and  
16 bites because they are so bulky and so poorly  
17 retentive that patients do not stay with them. They  
18 will if they get it fit right, if they are very lucky.  
19 But because of arch sizes, where some patients have  
20 extremely wide arches and others don't, the boil and  
21 bites don't fit everybody. It's very hard to find  
22 them. Unless you're looking at a white female, small

1 white male, it's hard to find boil and bites to fit.

2 CHAIRPERSON GULYA: Okay. Well, I would  
3 like to thank Dr. Terris and Dr. Demko for some highly  
4 illuminating presentations. They certainly brought  
5 into focus some of the issues and also complemented  
6 the materials provided by FDA staff.

7 PANEL DELIBERATIONS

8 CHAIRPERSON GULYA: According to my math,  
9 which is always suspect, -- so I am willing to stand  
10 and listen to corrections -- I think we have about 75  
11 minutes now to start going through some of these  
12 questions.

13 And I am reminded a little bit of the  
14 labors of Hercules. I will remember to thank the FDA  
15 for giving us such a nice task to keep us busy.

16 That having been said, in all seriousness,  
17 I would like to see us try and tackle question number  
18 1. I think looking at it at one big clump, it seems  
19 insurmountable. But I think if we break it down to  
20 the little bits, we can kind of chip away at it. And  
21 hopefully if we chip away at it, we might even get it  
22 done by lunch, by 12:30.

1                   What I propose we do is in a roundtable  
2 fashion so that every panel member has an opportunity  
3 to speak his or her mind, I would like to go through  
4 each device and have each panelist discuss their  
5 risk-benefit analysis with respect to the different  
6 indications.

7                   So, for example, for the tongue retaining  
8 device, if we could just go through the risks and  
9 benefits of snoring and then through the different  
10 stages of obstructive sleep apnea.

11                   And I think if we keep in mind that we  
12 probably have about 10-15 minutes for each device and  
13 note that probably some devices will require a little  
14 bit more time, some devices probably a little bit less  
15 time, I think we can kind of in our own heads kind of  
16 adjust how much verbiage we give to each one of these.

17                   So let me see now. Why don't we start  
18 with Mr. Crompton.

19                   MR. CROMPTON: Yes. This is Mike  
20 Crompton. I'm going to limit my discussion to the ENT  
21 devices and then defer to my colleague here for the  
22 dental devices.

1 I think based on the presentations we  
2 heard this morning, the risk profile for the ENT  
3 devices is obviously less of an issue compared to the  
4 dental devices. However, the definitional aspects are  
5 something that I think I need clarification on and  
6 industry as well in terms of these classifications for  
7 obstructive sleep apnea, primarily the differentiation  
8 between moderate and severe. So we would look to the  
9 panel, the clinicians here, to offer some guidance on  
10 that.

11 Also, we are going to defer and wait for  
12 Dr. Mann's presentation on the mandibular support  
13 devices, which he alluded to he was going to discuss  
14 that because that, frankly, could be a device that  
15 could be of some value OTC for the OSA indication as  
16 well.

17 So I think those are the general comments  
18 we have on the devices at this point.

19 CHAIRPERSON GULYA: Okay. It sounds like  
20 your name was called.

21 DR. MANN: I just wanted to point out that  
22 we are not going to have any further discussions of

1 the mandibular support devices, that we just brought  
2 that up because we have received queries from industry  
3 as to what would be necessary in terms of clinical  
4 data to support an indication for obstructive sleep  
5 apnea or snoring with those devices. We have not  
6 received any 510(k)'s for those to date, but based on  
7 the queries, we thought it was reasonable to at least  
8 raise it as a possible device that we may be seeing at  
9 some point in the future.

10 MR. CROMPTON: Okay. That clarified that,  
11 then.

12 CHAIRPERSON GULYA: Okay. Thank you. Mr.  
13 Schechter?

14 MR. SCHECHTER: This is Dan Schechter. I  
15 had some consultations with various members of  
16 industry. The comments that I have received are  
17 somewhat mixed, but I think I would encourage the  
18 panel to consider if there are perhaps a subset of  
19 these devices, even within one of these three dental  
20 device categories that would be suitable for OTC use.

21 I think it is probably generally  
22 recognized that there are devices, professional

1 devices, that simply are too complex or too active in  
2 terms of their activity in the mouth to be used over  
3 the counter. But, on the other hand, there are  
4 devices that might lend themselves more easily to OTC  
5 use. I would encourage the panel to try and find that  
6 subset here today.

7 CHAIRPERSON GULYA: Let's just try and  
8 look at the tongue retaining device in terms of the  
9 risk-benefit analysis for snoring and obstructive  
10 sleep apnea. I think we can just focus on that for  
11 now and maybe just pass if you feel you do not wish to  
12 comment on that. Ms. Howe?

13 MS. HOWE: I appreciate the opportunity to  
14 represent consumers to both the Dental and the ENT  
15 Panels and hope that in reviewing the tongue retaining  
16 device and other devices, that we look at the safety  
17 and the efficacy but also access to care, that we're  
18 talking about a large group of people if we do look at  
19 snoring, a large population, who will not readily go  
20 to their dentist or their medical professional for  
21 treatment. And they're seeking some form of treatment  
22 resolution to their problem and also some education

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1 about it.

2 I would like to refer back to the  
3 individual who spoke about the opportunity that an  
4 over-the-counter product might give people to learn  
5 more about what is snoring and, in fact, help in the  
6 screening process of OSA.

7 In referring to one product or the other,  
8 I certainly have to defer to the specialists here, who  
9 can talk more about the manufacturers' products that  
10 they're using or placement, fit, and adjustment  
11 abilities for an over-the-counter product. But,  
12 again, hopefully everybody will take into  
13 consideration access to care for people who would not  
14 normally be going to see a professional for their  
15 snoring problem.

16 CHAIRPERSON GULYA: Thank you.

17 Dr. Stern?

18 DR. STERN: I'm sorry. Could you please

19 --

20 CHAIRPERSON GULYA: Sure. We're looking  
21 at the tongue retaining device, question number 1,  
22 looking at the risks versus the benefits of allowing

1 it to be marketed as a device for snoring, obstructive  
2 sleep apnea. What are your thoughts?

3 DR. STERN: That's a tough question, I  
4 think, because it seems like it has to be a product  
5 that has to be fit a certain way. Consumers have to  
6 be educated regarding putting their tongue in and  
7 retaining it and the side effects and things like  
8 that.

9 As far as snoring, we need to make sure  
10 that there are some sort of screens that tell me,  
11 "Okay. I'm snoring" and then have a partner or  
12 somebody that is going to be able to listen to what is  
13 going on, a family member. You need another person  
14 involved somehow or a tape-recording device to find  
15 out exactly what is going on, "Why am I having this  
16 problem?" It seems like it's a multifactorial thing  
17 here.

18 It seems to me also that the lack of  
19 public awareness is a significant issue with regard to  
20 this. Even myself as a physician, I was not aware  
21 that this was something that would be an option to  
22 recommend to patients.

1           So I think lack of public awareness is a  
2           significant issue here. And I am not convinced that  
3           if there is something that is going to be made over  
4           the counter, then are there enough documented studies?

5           It seems like most of these things have a  
6           fairly small number of patients. And so if it is  
7           going to be made over the counter, I would recommend  
8           that it probably be recommended that it be tried over  
9           the counter and then see what studies have been done  
10          to show that this is a modifiable appliance that can  
11          be even used and that patients are able to understand  
12          the impact and the significance and the indication for  
13          being able to be used and that it is understood that  
14          this is recommended only for snoring and maybe not for  
15          obstructive sleep apnea and that the risks and the  
16          benefits and alternatives are also explained in lay  
17          language and whether or not this would be a product  
18          that would be easy to use. It's just something you  
19          just put it in your mouth and then stick your tongue  
20          in here. And this is what you do, and it's used for  
21          a certain amount of time. Is this something that's  
22          going to be easy to use, easy to adjust? And I'm not

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1 sure that I am convinced that that is the case yet at  
2 this time.

3 CHAIRPERSON GULYA: Thank you very much.  
4 Dr. Zero?

5 MEMBER ZERO: Domenick Zero, Dental  
6 Products Panel. I will give a qualified response in  
7 that I am not an expert in this area, and I am  
8 learning a lot about it. It is a very fascinating  
9 area.

10 This may apply to all of these devices  
11 that are under consideration. The first issue is  
12 diagnosis. I don't understand how a patient or an  
13 individual can make an appropriate diagnosis as to the  
14 condition they have, the severity of that condition,  
15 and then following from that the appropriate treatment  
16 decisions to manage that condition. I just don't. In  
17 something as complicated as this and something as  
18 serious as this, I don't see how an individual can  
19 make that decision from an over-the-counter product.

20 The other issue is monitoring. It is  
21 obvious that there are a number of untoward effects  
22 that can occur that can be at least controlled and

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1 modified if a professional is involved, a dental  
2 professional is involved with that use of the device.  
3 I don't see how an individual can properly monitor the  
4 symptoms, the changes that could occur in their mouth  
5 over time and do that in a way that would prevent a  
6 serious complication.

7 So with that, I see the risk-benefit to be  
8 really on the side of too much risk and not enough  
9 benefit.

10 CHAIRPERSON GULYA: Thank you very much.

11 Dr. Li?

12 DR. LI: I concur in terms of the  
13 diagnosis. I see approximately 30 new sleep patients  
14 a week. And I perform sleep studies on all of them.  
15 Even for well-trained physicians in terms of  
16 specializing sleep, I'm often surprised at the  
17 severity of the disease with their objective testing.

18 So I think it would be in error to approve  
19 an OTC device that "treats" sleep apnea without a  
20 physician evaluation and to really look into the  
21 severity of the problem. That's number one.

22 In terms of a tongue retaining device, my

1 understanding of the literature is that the result is  
2 actually fairly mixed. And that goes along with some  
3 other devices as well. So in terms of efficacy, I  
4 think before even approving that as an OTC device, we  
5 will have to look at the effectiveness of the device.

6 CHAIRPERSON GULYA: Could you please  
7 address the issue of snoring? I just heard about OSA.

8 DR. LI: I think in terms of, well, the  
9 first issue, I think for the layman, you need to  
10 separate the issue between snoring and sleep apnea.  
11 In terms of snoring, I think it's reasonable for a  
12 tongue retaining device to probably be approved for  
13 snoring, but in terms of fabrication, the  
14 effectiveness, I think it would be a pretty  
15 challenging issue for the manufacturer to make it  
16 effective for snoring improvement.

17 CHAIRPERSON GULYA: Okay. Thank you.

18 Dr. Jenkins?

19 MEMBER JENKINS: I would think in terms of  
20 snoring that the risk-benefit ratio would be better in  
21 that it can control that and if the changes in  
22 dentition are monitored, then it could possibly be,

1 you know, that caveat needs to be into labeling that  
2 they need to have monitoring and possible changes in  
3 their dentition.

4 However, in obstructive sleep apnea, since  
5 we as physicians have trouble making this diagnosis,  
6 to have a patient make this diagnosis and use it as an  
7 across-the-counter device on their own, that I think  
8 would be very difficult. And the risk-benefit ratio  
9 would be very negative.

10 CHAIRPERSON GULYA: Thank you.

11 Dr. Suzuki?

12 MEMBER SUZUKI: Jon Suzuki, Dental  
13 Products. I guess one of my major questions would be  
14 if the tongue retaining devices were, in fact, OTC,  
15 would it increase at all the risk for either  
16 aspiration or partial obstruction of airway? I don't  
17 believe I have heard data representing either side.

18 CHAIRPERSON GULYA: From my read of the  
19 literature we were provided, I would have concerns of  
20 providing this as an OTC device, certainly for the  
21 OSA, for reasons that have been already suggested in  
22 terms of the difficulty of even us making diagnoses

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1 with sophisticated equipment.

2 For snoring, again, I am not convinced  
3 that there is data showing sufficient efficacy. So  
4 that would be I would have concerns on all fronts  
5 regarding the tongue retaining device.

6 Dr. Zuniga?

7 MEMBER ZUNIGA: John Zuniga. I'm coming  
8 from the point of view of that of a person with  
9 clinical experience with patients, but from listening  
10 to what has been presented here --

11 EXECUTIVE SECRETARY S. THORNTON: Excuse  
12 me, Dr. Zuniga. Could you please speak into the  
13 microphone a little bit more?

14 MEMBER ZUNIGA: I'm sorry. From reviewing  
15 what I have heard today and the provided information,  
16 I think it is quite clear that the tongue devices for  
17 OSA do not provide the benefit versus the risks that  
18 it can ensue. And, similarly for snoring, the  
19 information is minimal for efficacy. So I think that  
20 for both cases, the risks are higher than the  
21 benefits.

22 CHAIRPERSON GULYA: Thank you.

1 DR. MAIR: Eric Mair, San Antonio. In  
2 typical vice presidential debate fashion, I think I  
3 want to answer one other question first from the  
4 industry.

5 (Laughter.)

6 DR. MAIR: The question was, what is the  
7 difference -- I mean, this is important -- between  
8 mild, moderate, and severe apnea and how that effects  
9 because we really need to know what those definitions  
10 are.

11 The AASM has come out with these  
12 definitions. And mild is between 5 to 15 apnea or  
13 hypopnea events per hour. Moderate is 15 to 30. And  
14 severe is greater than 30. It's important to know  
15 those are more than just numbers. There's no adequate  
16 prospective study that has validated the severity  
17 criteria for any of this. And the reason for the  
18 severity criteria is based on some data from the  
19 Wisconsin Sleep Cohort that showed an increased risk  
20 of hypertension with an AHI of approximately 30.

21 So to distinguish mild to moderate apnea  
22 is a very difficult thing to do. And it's not based

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1 on really good science. To throw another wrench into  
2 everything, too, we talk about -- in all of the  
3 studies that we have presented so far today have  
4 mentioned that the gold standard is the polysomnogram.  
5 We do everything based on the polysomnogram. I think  
6 that we know now that the gold standard is a little  
7 bit tarnished.

8           Some of the studies that we have been  
9 doing and many others have been doing, too, have  
10 looked at the variance of reader to reader of  
11 polysomnogram and the night-to-night variation. These  
12 can be greater than 30 percent in multiple studies,  
13 including ours.

14           What this means is that one question asked  
15 I think by John is, what happens if someone has severe  
16 apnea? Can they have mild apnea afterwards? I think  
17 David's answer was only after some sort of therapy,  
18 not necessarily so. It's so dependent on the study  
19 itself, where it's done, how it's read. There are  
20 some problems in this area.

21           Back to the question at hand, tongue  
22 retaining devices I strongly feel should not be over

1 the counter, mostly for reasons that there are  
2 different manufacturers of these, that for the patient  
3 to squeeze the tongue and give negative pressure on  
4 the tongue so that there's going to be venous  
5 congestion of that area, we're concerned about airway  
6 edema, airway problems if these things intermittently  
7 fall off in the middle of the night if there is too  
8 much negative pressure on these things. They could  
9 cause some significant tongue edema, which from a  
10 surgeon's point of view, from ENT, that's one of the  
11 problems that we deal with. We could see this  
12 definitely over the counter. And just on tongue we're  
13 talking about right now.

14 Let me pass it on to the next vice  
15 presidential candidate.

16 CHAIRPERSON GULYA: Dr. Orloff?

17 DR. ORLOFF: Thank you. Lisa Orloff.  
18 Just sort of an extension of what you just said, Eric,  
19 if there is such variation in the interpretation of  
20 polysomnography or variation from one night to the  
21 next, I guess we have to look at whether our follow-up  
22 polysomnograms after treatment are really reflecting

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1 an improvement or a lack of improvement adequately  
2 with any of these devices.

3 Specifically addressing the tongue  
4 retaining device and snoring, not sleep apnea but  
5 snoring, from what I have heard today and from what I  
6 have read, I have gotten the impression that the  
7 tongue retaining device is the least favorable oral  
8 appliance relative to the mandibular repositioning  
9 device. And I'm not sure about comparison directly  
10 with the palatal lifting device.

11 My fear if the tongue retaining device  
12 were to be over-the-counter -- and I think we'll be  
13 discussing the other devices more next -- are likely  
14 to not be supported for obstructive sleep apnea use by  
15 this panel, that more patients would be selecting the  
16 one product that is available over-the-counter, being  
17 the tongue retaining device, when it is actually  
18 appropriate for what sounds like the smallest subset  
19 of patients with snoring. So I would oppose having it  
20 be available over the counter.

21 CHAIRPERSON GULYA: Thank you.

22 Dr. Woodson?

1 DR. WOODSON: Yes. Gayle Woodson. I'm  
2 pretty much in concurrence with everybody who has  
3 talked so far in terms of what is the best thing in  
4 terms of an ideal world where everybody can go to the  
5 doctor and get their sleep study and know these  
6 things.

7 I think we live in a world where not  
8 everybody in the country has health insurance. Even  
9 those who have health insurance, many times their  
10 health insurance doesn't cover the cost of a sleep  
11 study or maybe it will pay for it if you get the sleep  
12 study and it turns out you have sleep apnea, it will  
13 pay for the study, but if not, it's out of your own  
14 pocket. So there are definite economic things we have  
15 to think about.

16 So when we treat patients, even in our  
17 office, with snoring, sometimes we go ahead and treat  
18 snoring because there are not the resources to do the  
19 sleep apnea testing.

20 So if you think about that the major risk  
21 of a lot of these snoring treatments is that 25  
22 percent of them could have sleep apnea, well, that may

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1 be just a -- otherwise, if we're dooming everybody to  
2 continue suffering with snoring without trying  
3 anything else, if we deny all snoring treatments  
4 because they should have sleep testing, I don't think  
5 I have enough evidence in here to tell me whether  
6 tongue retaining devices help snoring. I think there  
7 are some patients that it probably would work with and  
8 some that it wouldn't.

9 I think, rather than saying a blanket "No,  
10 no tongue retaining device should be over the counter"  
11 or "Yes, they all should," I think that they would  
12 have to be on an individual basis of looking at the  
13 data for each device and having real clear labeling,  
14 telling people if somebody knows you stop breathing,  
15 although with the labeling, the warnings, the caveats.

16 I think we have to be careful about  
17 blocking people from being able to try something that  
18 doesn't have a lot of down side risk from the  
19 appliance itself.

20 CHAIRPERSON GULYA: Dr. Terris?

21 DR. TERRIS: In response to Eric Mair's  
22 comments, I was going to suggest that I could be Dick

1 Cheney and maybe you would be John Edwards when, in  
2 fact, it doesn't work because we totally agree.

3 And so your criticism of polysomnography  
4 is one of my favorite topics to talk about. I didn't  
5 discuss that in my 12-minute presentation that I was  
6 allocated this morning, but yes, the so-called gold  
7 standard is the best we have. But there are a lot of  
8 problems with it, unquestionably.

9 I don't think you would argue that it is  
10 still the best we have. I think we still need to rely  
11 on it the best we can. I love how they report out the  
12 numbers, 33.67 events per hour. When you actually see  
13 how it is scored, with due respect to Dr. Epstein,  
14 there is a lot of wiggle room in these numbers, but it  
15 doesn't look like it when you get the study because it  
16 looks very scientific.

17 In terms of the tongue retaining device,  
18 in particular, my reluctance -- and I was impressed to  
19 hear Kasey Li say he would be okay with it as an  
20 over-the-counter device for snoring because the  
21 problem with that, if you think it through, how do you  
22 know if the patient only has snoring? If you make it

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1 over-the-counter, the patient does not have to present  
2 to their doctor and get a sleep study. So they may  
3 think they only have snoring, but they may have a much  
4 more serious disease.

5 So I agree that if we knew they had  
6 snoring, I would say, "Okay." But if know they only  
7 have snoring, then yes, I would be okay with some of  
8 these devices. But the problem is if you make it  
9 over-the-counter, you will never know. And you will  
10 miss an opportunity to take care of a much greater  
11 population of patients.

12 That gets to my third issue, which is  
13 access. I'm glad Elizabeth and Gayle have pointed  
14 that out because that is a huge concern of mine in  
15 terms of reaching out to more and more patients. To  
16 me, that is an argument for visiting the issue of a  
17 reasonable screening device that will capture more  
18 patients and help them identify that they have a  
19 problem.

20 But I don't want to put the cart before  
21 the horse and say, "Well, we don't know if you have  
22 sleep apnea. We can't afford to identify if you have

1 it. So let's give you a cheap way of maybe treating  
2 it that a few studies with a small number of patients  
3 suggest is effective." To me, that is doing those  
4 same patients that we want to help a disservice.

5 So it's a laudable goal, and I think there  
6 are ways to achieve that eventually, but I think  
7 making any of these devices, I'm impressed that the  
8 nasal Breathe Right strip got over-the-counter  
9 approval to treat snoring and sleep apnea because I  
10 worry about all of the patients that should be coming  
11 into the office and don't.

12 CHAIRPERSON GULYA: Thank you.

13 Dr. Calhoun?

14 DR. CALHOUN: I concur with those who are  
15 in favor of not making this an over-the-counter  
16 device. My biggest concern is the risk of a missed  
17 diagnosis and a missed opportunity for intervention  
18 because even I as a professional who deals with sleep  
19 apnea patients can't make that diagnosis based on  
20 history and physical exam alone. There is no way that  
21 a patient can. And to miss this opportunity for  
22 intervention for a disease process that has long-term

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1 cardiovascular consequences I think would be a  
2 mistake.

3 Now, the one thing we haven't mentioned is  
4 how much of a parallel there is between disappearance  
5 of the sound of snoring with the treatment with these  
6 devices and changes in the RDI. If we could  
7 definitively show that someone who snored who was  
8 treated with a tongue retaining device or a mandibular  
9 device and the snoring disappeared and that correlated  
10 with a disappearance of measurable apneas on a sleep  
11 study, then I think we would have to revisit this  
12 question.

13 CHAIRPERSON GULYA: Thank you.

14 Dr. Demko?

15 DR. DEMKO: Gail Demko. What I look at is  
16 how effective are tongue retaining devices. The  
17 studies that have been done with them have been very  
18 small numbers. They look at only adults. They will  
19 say that patients with mandibular repositioners  
20 because I am going to skip to that for a second are  
21 treated. We can stop snoring in about 75 percent of  
22 patients in a mandibular repositioner. We cannot fix

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1 their sleep apnea above 62 percent is what stats run.  
2 Tongue retaining device is much lower.

3 If a tongue retaining device were to go  
4 over the counter, it would be easy to label, easy for  
5 the patient to use. You're looking at very few  
6 patients are going to be really effectively treated  
7 with snoring more so than with obstructive sleep  
8 apnea.

9 So if it were snoring only, I couldn't  
10 tell you one way or the other. Most of the patients  
11 I have don't even use their tongue retaining device.  
12 The compliance rate is very, very low.

13 CHAIRPERSON GULYA: Thank you. All right.

14 Yes, Dr. Mair? Dr. Rosenthal?

15 (No response.)

16 CHAIRPERSON GULYA: All right. I think we  
17 have covered a lot of broad-ranging issues here. I  
18 heard basically from the panel that there was a  
19 distinct lack of enthusiasm for approving the TRD for  
20 over-the-counter use for any kind of obstructive sleep  
21 apnea. There was perhaps a little bit of acceptance  
22 of it for snoring, although it was not overwhelming.

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1 And I hear a big issue in access to care. That is  
2 counterbalanced by appropriate diagnostic evaluation  
3 leading to appropriate care.

4 So, FDA, does this give you enough data to  
5 work with here? And then we'll move on to the  
6 mandibular repositioning devices.

7 (No response.)

8 CHAIRPERSON GULYA: Okay. Well, Dr.  
9 Demko, we will start off with you with the MRD. It  
10 will be a little bit of a continuation of your talk,  
11 but I think we have covered some of the issues. So in  
12 terms of specifically to the MRD, over-the-counter  
13 snoring versus obstructive sleep apnea, the  
14 risk-benefits. Sure? Dr. Jenkins?

15 MEMBER JENKINS: Admittedly, I'm an  
16 otologist, Herman Jenkins, and not a sleep apnea  
17 surgeon or anything like that, but it seems to me that  
18 a lot of people who snore do not have obstructive  
19 sleep apnea.

20 What percentage are we talking about of  
21 snorers? I dare say a large percentage of people in  
22 this room at this age start snoring. Is there a

1 population out there that just has snoring that needs  
2 to be treated or do they all have some degree of  
3 obstructive sleep apnea?

4 I don't know that answer. Dave, can you  
5 tell us that breadth?

6 DR. TERRIS: Can I answer?

7 CHAIRPERSON GULYA: Sure. Go ahead, Dr.  
8 Terris.

9 DR. TERRIS: Thank you.

10 First of all, I would say what we try to  
11 do in sleep is not think about this diagnosis, that  
12 diagnosis, that diagnosis because it is a spectrum of  
13 disease from snoring, what we call primary snoring,  
14 through upper airway resistance syndrome through mild  
15 sleep apnea, et cetera. So it's one big spectrum, as  
16 opposed to you have snoring or you have sleep apnea.

17 Having said that, probably two-thirds of  
18 patients that present with snoring have just snoring.  
19 Maybe a third have sleep apnea or something or that  
20 have snoring, not that present to a physician's  
21 office, because if you are prompted to come into a  
22 physician's office because of snoring, the chances

1 that you have sleep apnea are very high. But if you  
2 look at all patients out there that snore -- and it  
3 depends how you define snoring. Is it habitual? Is  
4 it every night, et cetera? I would say the majority  
5 do not have sleep apnea. I would acknowledge that.

6 MEMBER JENKINS: So does everyone whose  
7 bed partner complains about their snoring need a sleep  
8 study or should they just try some sort of appliance  
9 initially if they want to?

10 DR. TERRIS: Well, that's the \$64,000  
11 question. To me, I would say what they need is a  
12 screening test, not a full sleep study maybe, which is  
13 a \$2,000 study. But in the absence of that, I would  
14 say -- and, interestingly enough, I was reading in a  
15 newspaper flying up here that Medicare is on the brink  
16 of approving ambulatory sleep --

17 CHAIRPERSON GULYA: It has approved.

18 DR. TERRIS: Sorry?

19 CHAIRPERSON GULYA: I thought it had  
20 approved it.

21 DR. TERRIS: Has it been approved?

22 CHAIRPERSON GULYA: That's what I

1 DR. TERRIS: Okay. Well, maybe they have  
2 approved. So Medicare is now going to pay for  
3 ambulatory sleep studies, which are 3 or 4 hundred  
4 dollars, instead of \$2,000.

5 DR. MAIR: Dave, that hasn't, actually.

6 CHAIRPERSON GULYA: Oh, it hasn't?

7 DR. MAIR: No.

8 DR. TERRIS: Yes. I understood it to be  
9 considered, but it is probably going to happen.

10 DR. MAIR: It was considered last week.  
11 The final decision hasn't been made on it.

12 DR. TERRIS: Right. But, anyway, that  
13 looks like they probably will approve it, in which  
14 case you would have a reasonable cost way of  
15 identifying whether or not you have snoring.

16 I mean, I had snoring. I wanted to get a  
17 sleep study because I wanted to know, am I at risk for  
18 significant cardiovascular disease. So I guess I  
19 answered the question to myself.

20 CHAIRPERSON GULYA: Okay. I want to make  
21 sure we get through these things here. Burning  
22 issues? Yes?

1 DR. MAIR: Just very quickly to answer Dr.  
2 Jenkins' question, snoring is reported in 40 to 60  
3 percent of the population. With AHI levels greater  
4 than 5, that apnea then will be present in about 24  
5 percent of men and 9 percent of women. When you look  
6 at AHI levels greater than 15, then you are going to  
7 say maybe about 4 percent of men and women or maybe 9  
8 percent of men and 4 percent of women.

9 The numbers are fuzzy. And just the  
10 question that you have is a real question. And it's  
11 based on our definitions of mild and knowing what mild  
12 obstructive sleep apnea is. But the snorers are a  
13 significant population.

14 CHAIRPERSON GULYA: Okay. Great. Thank  
15 you.

16 MEMBER JENKINS: I think this is really a  
17 crucial thing here in this discussion if we are  
18 talking about these individual things. What  
19 population are we treating? If you're talking about  
20 75 percent of these people snoring, not really having  
21 obstructive sleep apnea, then it is a different story  
22 how you are going to look at these devices. What is

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1 the risk of this device versus potentially getting any  
2 benefit from it?

3 If only 20 percent of the people with a  
4 tongue retaining device get benefit, should it be  
5 available across the counter? Let them try it out.  
6 They may spend \$30 on that and find it works or it  
7 doesn't work and throw it away.

8 I think that is a crucial thing here, what  
9 is going on. If the change in dentition is  
10 significant enough or the other risks, that may be  
11 there to warrant having it across the counter or not.

12 I think we have got to really look at what  
13 is our population here. It is a very crucial thing.  
14 Not everybody who snores has sleep apnea is what we  
15 are saying. Actually, a small percentage of them have  
16 sleep apnea that is significant.

17 DR. TERRIS: Not exactly. Can we just  
18 make one more comment? On the flip side, if you have  
19 these patients with snoring that don't get treated, I  
20 mean, when Elizabeth talks about access to medical  
21 care, I think she is not talking about treating a  
22 disease like pure snoring, which is not really a

1 significant health risk relative to sleep apnea.

2 So if they don't have access to treatment  
3 for their snoring, they don't have access to treatment  
4 for their facelift, that is not as significant as not  
5 having access to treatment for sleep apnea, I would  
6 say.

7 MEMBER JENKINS: This doesn't deny them  
8 access.

9 DR. WOODSON: This is a real critical  
10 issue. And to compare snoring to say, "Well, we are  
11 not going to allow you to pay \$30 for a tongue  
12 retaining device over the counter because you might  
13 have sleep apnea" is different than telling somebody,  
14 "Well, you know, your face is going to be wrinkled  
15 unless you have a facelift." It's a totally different  
16 issue.

17 Somebody with a headache might have a  
18 brain tumor. So should you have to get an MRI and not  
19 be allowed to buy aspirin? These are the kinds of  
20 issues we are talking about here.

21 CHAIRPERSON GULYA: Okay. I think that  
22 was a very useful discussion. Yes, Dr. Stern?

1 DR. STERN: And then we also have the  
2 dilemma of many partners that sleep with patients who  
3 snore and the destruction of their sleep, not just the  
4 person who is snoring. So you are talking about a  
5 fairly large percentage of people that are being  
6 affected, not just the snorer alone.

7 CHAIRPERSON GULYA: Okay. Great.

8 DR. WOODSON: Sometimes the neighbors.

9 (Laughter.)

10 CHAIRPERSON GULYA: I'm not going to go  
11 down that road.

12 Dr. Demko, back to the mandibular  
13 repositioning device.

14 DR. DEMKO: Basically with the mandibular  
15 repositioning devices, I find the side effects are  
16 much more significant than they are with any of the  
17 tongue retaining devices I have seen. They are also  
18 much more effective.

19 Therefore, because the majority of the  
20 side effects are completely controllable except for  
21 that tooth movement as we get out, the big problems  
22 are that at two years, three years, four-year

1 follow-up, the same with the tongue retaining device,  
2 you are not going to see tooth movement for two years.

3 None of the studies go that far out except  
4 these new ones coming in. I think that with the  
5 mandibular repositioning device, the negative side  
6 effects far outweigh the positive aspects because a  
7 dentist really can control most of the problems if  
8 they are in the care of a decent dentist who knows  
9 what is going on.

10 CHAIRPERSON GULYA: Okay. Thank you.

11 DR. CALHOUN: Karen Calhoun. The crux of  
12 the matter, I think, is what happens to the patient  
13 with moderately severe sleep apnea who has access to  
14 and buys an over-the-counter device? The snoring is  
15 diminished to the point where it is socially  
16 acceptable. And severe sleep apnea is never addressed  
17 or treated.

18 Herman, there is a spectrum from  
19 occasional snorers through habitual snorers through  
20 habitual loud snorers. I think just the fact that  
21 there is a relatively low incidence among snorers of  
22 sleep apnea is not a reason to ignore obtaining

1 appropriate treatment for those patients.

2 When you think about what the yield is of  
3 MRs looking for acoustics, it is not extremely high,  
4 but it is still something that is very reasonable  
5 medically to do.

6 CHAIRPERSON GULYA: Dr. Terris?

7 DR. TERRIS: Let's use another analogy in  
8 otology for Dr. Jenkins. It's like I found my Mr.  
9 Edwards over there. And I'm tossing this around in my  
10 head as well because I think we have all had some  
11 interesting things to think about. Would you  
12 recommend patients have access to hearing aids in such  
13 a way that they do not need an audiogram before  
14 getting their hearing aid? To me, it seems like a  
15 similar issue.

16 Let's just say that audiograms were \$500  
17 and a hearing aid were \$30, instead of the way it is  
18 now. Would you say, "Oh, they can just get a hearing  
19 aid because we know they have hearing loss. It's  
20 cheap. Let's go ahead and treat that"?

21 MEMBER JENKINS: Can I rebut these two?

22 CHAIRPERSON GULYA: As long as they are

1 seated in the chair.

2 MEMBER JENKINS: I think a better analogy  
3 is reading glasses, which you can buy at the five and  
4 dime. They work great for some people, and that's all  
5 they need, is to pick up a 2X reading glass like the  
6 person on your right. They work fine.

7 We are talking about a large population,  
8 many of which are not going to go see a physician and  
9 get diagnosed for snoring. Their wife is going to  
10 complain about it. He is going to ignore it. I have  
11 this in my household. She brings home the Breathe  
12 Right stirps and all this sort of thing.

13 There are a lot of people who have a  
14 simple problem they're looking to be solved. The  
15 question is, in solving that simple problem, the risk  
16 that we put them in with these devices, does that make  
17 it worthwhile?

18 Now, if you're going to move the mandible  
19 out a centimeter or two, change their occlusion, et  
20 cetera, yes, your risks are quite significant there,  
21 even though your benefits are also very significant.

22 So then it becomes a question, should you

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1 have that across the counter? If it doesn't do much  
2 damage and it helps them, granted they haven't been  
3 diagnosed, but a lot of people don't go get diagnosed  
4 anyhow. You've got to realize that. You're treating  
5 a symptom here. That's what is being labeled by the  
6 company, to treat a symptom for snoring, not for  
7 diagnosis of sleep apnea.

8 CHAIRPERSON GULYA: Dr. Woodson?

9 DR. WOODSON: I agree with everything  
10 Herman said, but I'm not going to pursue that issue.  
11 I am sure it is going to come up again and again  
12 because it is a huge issue here.

13 But just to say mandibular repositioning  
14 device, I just had to see that one picture of the  
15 woman who bought one over the internet from England.  
16 It seems like the long-term effects of the mandibular  
17 repositioning device are such that it really shouldn't  
18 be used over-the-counter.

19 CHAIRPERSON GULYA: Thank you.

20 Dr. Orloff?

21 DR. ORLOFF: Lisa Orloff. As Dr. Woodson  
22 said, I think some of these arguments are going to go

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1 around and around, but the more complex the device,  
2 the greater the potential for side effects and harmful  
3 side effects, such as the mandibular repositioning  
4 device.

5 I think the more the risk-benefit balance  
6 is tipped toward risk and the more the MRD is just a  
7 much more complex device in itself, the fitting, the  
8 adjustment, the dental as well as other oral  
9 ramifications, I think require the involvement of a  
10 health care professional.

11 CHAIRPERSON GULYA: Wonderful. Thank you.

12 Dr. Mair?

13 DR. MAIR: Eric Mair. As a consumer, I  
14 would look at the mandibular repositioning device as  
15 the bite-and-block. I would say this looks great.  
16 This is something very inexpensive. This is the way  
17 to go. I agree with what Dr. Jenkins is saying.

18 But I think that from what we have heard  
19 today and from the articles that we have been reading,  
20 there are some notable complications associated here,  
21 notable complications potentially to the airway, to  
22 the jaw, to the tongue, to the teeth. We have to look

1 at potential complications in order to protect the  
2 consumer, even though the consumer may not know about  
3 these.

4 I am not in agreement with the mandibular  
5 repositioning devices for over-the-counter for  
6 snoring, mild apnea, or moderate apnea. We need to  
7 follow up, and we need to care. I think that is our  
8 greatest thing: to think about our patients first.

9 CHAIRPERSON GULYA: Thank you very much.

10 Dr. Zuniga?

11 MEMBER ZUNIGA: I think that what has been  
12 presented in the literature suggest that the  
13 mandibular repositioning devices are effective for  
14 both snoring and OSA in a range of patients. That  
15 would make them very useful for clinical practice.  
16 However, they are subject to adverse events, most of  
17 them short-term but some long-term.

18 However, what we have heard from about  
19 that data is generally from the prescription devices.  
20 I have not heard any information about the boil  
21 over-the-counter devices and that information  
22 correlates. So we're assuming there's a correlation

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1 between the two devices, that because it's boil  
2 technique, it's worse than the prescription. So  
3 that's an assumption that the risks are greater than  
4 the benefits.

5 On the other hand, I think someone earlier  
6 spoke about clenching and some of the bruxing devices  
7 that are available over the counter currently. We  
8 can't make that correlation because that disorder is  
9 a self-limiting disorder with very little long-term  
10 effects for the general population with TMJ.

11 My understanding from the discussion is  
12 OSA is a significant problem with that, progressive.  
13 So it is important that the diagnosis and, therefore,  
14 the treatment be effective. So my concern because of  
15 that and the degree of adjustments that are required,  
16 the risks still outweigh the benefits. But there's  
17 still not enough information.

18 CHAIRPERSON GULYA: Thank you.

19 Dr. Runner?

20 DR. RUNNER: I just wanted to make one  
21 comment. This is Susan Runner. There may be devices  
22 that are sold over the counter as bruxism devices.

1 They are not legally marketed as bruxism devices. We  
2 have not cleared any devices as such.

3 CHAIRPERSON GULYA: Oh, okay. I tend to  
4 agree with the previous speakers for the --

5 EXECUTIVE SECRETARY S. THORNTON: Dr.  
6 Runner, could you repeat that? I'm afraid it didn't  
7 get caught by some of us.

8 DR. RUNNER: I'm sorry. There are no  
9 legally marketed anti-bruxism devices on the market.

10 CHAIRPERSON GULYA: I think two things  
11 struck me. One was Dr. Demko's statement to the fact  
12 that some of these dentition changes with the MRDs are  
13 irreversible. My read of the literature we have been  
14 provided had indicated that they were perhaps  
15 reversible, but the irreversibility gave me pause.

16 The other thing that gave me pause was the  
17 fact that it seemed like the bite and block appliance,  
18 which would be the type that would be -- or the  
19 heat-and-use device, which would be maybe the most  
20 adaptable to the OTC, was basically the one that had  
21 the poorest retention and then one would assume have  
22 the poorest efficacy and also had the poorest

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1 compliance rate because it was so uncomfortable.

2 So my thought is that the one that would  
3 be most likely to be able to be an OTC device, the one  
4 that the patient would self-fit, seems also to be  
5 correlated with the fact that the one that is least  
6 likely to be used and least likely to be efficacious.  
7 So I guess I've got to throw my towel in on the OTC as  
8 being probably not appropriate for the MRDs.

9 Dr. Suzuki, are you going to be my --

10 DR. DEMKO: Can I make one comment?

11 CHAIRPERSON GULYA: Yes.

12 DR. DEMKO: Gail Demko. The article that  
13 is in here by Kathy Ferguson, "A Randomized Crossover  
14 Study of Oral Appliance in Nasal Continuous Positive  
15 Airway Pressure," is a boil and bite appliance. She  
16 used Snore-Guard. And it came up with it being 48  
17 percent effective, which is much less than. The  
18 custom fabricators run about 62 percent effective in  
19 treating mild sleep apnea.

20 CHAIRPERSON GULYA: Thank you.

21 MEMBER SUZUKI: Jon Suzuki, Dental  
22 Products. I believe the adverse dental implications

1 far outweigh the benefits. So I am not in favor of  
2 this product being OTC.

3 CHAIRPERSON GULYA: Okay. Thank you.

4 Herman, how do you feel?

5 (Laughter.)

6 MEMBER JENKINS: Well, I think, first of  
7 all, we need to be careful when we talk about what is  
8 less effective. The FDA has to decide whether the  
9 device is marketable. If it is 48 percent effective,  
10 then that is an FDA call with the labeling.

11 So we have to be careful in trying to use  
12 that as our criteria just saying it's less. You know,  
13 we have got to realize that we are talking about  
14 manufacturers here. There is a lot riding on this.  
15 So that's not really our call so much here.

16 I think the risk that has been shown to us  
17 here of permanent changes is significant with these  
18 devices. And to be used in long-term snoring or in  
19 obstructive sleep apnea without monitoring, et cetera,  
20 is not in the best interest of the patient. And the  
21 risk-benefit ratio becomes adverse at that point. I  
22 would agree that it should not go across the counter.

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1 CHAIRPERSON GULYA: Okay. Thank you.

2 Dr. Li?

3 DR. LI: Kasey Li. My comment is the same  
4 as the TRD device. I think the diagnosis is a crucial  
5 issue. Also, I have done orthomatic surgery for  
6 patients who have had long-term oral appliance use.  
7 The complications are great potentially. So I am not  
8 in favor of this OTC use for snoring or sleep apnea.

9 MEMBER ZERO: Domenick Zero. I still  
10 simply agree with what has been said here. I do not  
11 believe there is an adequate favorable risk-benefit  
12 ratio for this type of device and would not recommend  
13 OTC approval.

14 CHAIRPERSON GULYA: Wonderful. Thank you.

15 Dr. Stern?

16 DR. STERN: Again you have the issue of,  
17 you know, you're treating this for snoring or you are  
18 treating this for obstructive sleep apnea without  
19 adequate over-the-counter screening devices to see  
20 what exactly your problem is. However, if you do  
21 decide to do this over the counter, definitely you  
22 would say, you know, "If you do notice facial changes,

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1 see your doctor" or something to that effect and that  
2 "You should be following your doctor if you are going  
3 to try this over the counter." There is a 48 percent  
4 efficacy understanding that there will be some dental  
5 changes and cosmetic appearance changes and possibly  
6 bite issue changes.

7 So the issue of public responsibility for  
8 something like this, it seems to be much more  
9 effective compared to tongue retaining device for  
10 snoring and/or obstructive sleep apnea, but, again, I  
11 would caution that for mild to moderate obstructive  
12 sleep apnea, that that would not be my comfort level  
13 but for snoring, perhaps more so with the  
14 understanding that you need to be evaluated for  
15 obstructive sleep apnea if this is not working and the  
16 issue of if this is not helpful, please see your  
17 doctor and changes will happen.

18 CHAIRPERSON GULYA: Thank you, Dr. Stern.

19 Ms. Howe?

20 MS. HOWE: Betsy Howe. I agree the  
21 importance is not only the size of the population but  
22 also lifestyle issues, be it the people that you are

1 living with or sitting next to on an airplane.

2 I don't think we have to be over-academic  
3 about, are you snoring or are you not. I think the  
4 important issue is to indicate with a product, is this  
5 just for snoring or do you have to be aware that your  
6 snoring could lead to other more dramatic problems?  
7 And that is certainly something that we are able to  
8 recommend to the FDA, what the indication of the  
9 product is.

10 Regarding the MRD specifically, I think it  
11 would be of interest to know how a manufacturer could  
12 provide a one size fits all or if there are multiple  
13 sizes, how you can tell from the package if you are a  
14 small, medium, or large.

15 So I don't think that we right now are  
16 seeing the products that the manufacturers might  
17 provide to the public. And it would be very  
18 interesting to know if they can offer a product that  
19 moves the mandible enough to actually affect the  
20 snoring problem or if that product would cause damage  
21 if there is some way to have a truly cost-effective  
22 sizing that they can put on the market.

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1 CHAIRPERSON GULYA: Thank you.

2 Mr. Schechter?

3 MR. SCHECHTER: I'll try and save a little  
4 time by addressing the remaining five categories all  
5 at once, which is it seems pretty clear from the  
6 discussion that we are probably not going to recommend  
7 anything over the counter here for sleep apnea.

8 But I would suggest if it's a possibility  
9 from a regulatory standpoint that we perhaps admit the  
10 possibility that a particular device could have a  
11 risk-benefit analysis that would allow it to be  
12 marketed and leave that decision up to the FDA.

13 Obviously there are devices within all of  
14 these categories that present different risks. And to  
15 simply say that every tongue retaining device or every  
16 mandibular repositioning device could never be over  
17 the counter, I think, especially for snoring,  
18 regardless of whether there's a hidden sleep apnea  
19 problem, could have significant benefit with a limited  
20 risk and leave that determination up to the  
21 manufacturer with their submission, with their  
22 testing, and leave the ultimate decision up to the

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1 FDA.

2 CHAIRPERSON GULYA: Okay.

3 Mr. Crompton?

4 MR. CROMPTON: This is Mike Crompton. I  
5 would agree with Mr. Schechter and also the comments  
6 of our consumer reps, Dr. Stern and Ms. Howe, that  
7 certainly for the snoring indication -- and FDA has  
8 dealt with this before through labeling and education  
9 in the variety of tools that are available now.

10 We saw the Web site for cochlear implants.  
11 There are a variety of tools now that could be used.  
12 Of the categories of the dental devices, a fair  
13 reading of the literature, this was the most effective  
14 device that was in these peer-reviewed journals.

15 So, again, I don't think I would close the  
16 door certainly for the snoring indication for OTC for  
17 this device.

18 CHAIRPERSON GULYA: Okay. Thank you.

19 DR. ORLOFF: Can I ask just a quick  
20 question?

21 CHAIRPERSON GULYA: Dr. Orloff and then  
22 Dr. Calhoun. Okay.

1 DR. ORLOFF: Lisa Orloff. Since the boil  
2 and bite devices are available over the counter, as  
3 I'm understanding it, in places like England, is there  
4 any data from any of these other countries about  
5 either complications or success rates?

6 DR. DEMKO: Gail Demko. I've never seen  
7 any long-term data come in on any of these. So it  
8 certainly hasn't been published in the literature  
9 because I really follow that closely.

10 CHAIRPERSON GULYA: Dr. Calhoun?

11 DR. CALHOUN: I think that it is important  
12 to leave this with the possibility of looking at this  
13 question again, when there is a viable low-cost way to  
14 differentiate between snorers and snorers who have  
15 sleep apnea. Until we can make that differentiation,  
16 I think the risk of misdiagnosis is too great.

17 CHAIRPERSON GULYA: Okay. Thank you.

18 Moving to the palatal lifting device, I  
19 think I will change the order in which I am  
20 proceeding. And I will surprise Dr. Zuniga by asking  
21 him to go first.

22 MEMBER ZUNIGA: Thank you. I am now

1 awake.

2 I think that, again, from a review of the  
3 literature, my understanding of what was discussed  
4 today, which was very little on the palatal device, I  
5 don't think there is enough information to conclude  
6 its efficacy and/or any demonstration of its adverse  
7 events compared to the others.

8 So I would, in the one sense, withhold any  
9 comment, but I do have suspicion that the  
10 will be risks higher than the benefit.

11 CHAIRPERSON GULYA: Okay. I'll go to Dr.  
12 Suzuki, going to pop back and forth here a little bit.

13 MEMBER SUZUKI: Jon Suzuki, Dental  
14 Products. I agree with my colleague Dr. Zuniga.  
15 There is not enough evidence at this point in time.

16 CHAIRPERSON GULYA: Okay. Dr. Mair?

17 DR. MAIR: I would agree. No other  
18 further comments.

19 CHAIRPERSON GULYA: Dr. Jenkins?

20 MEMBER JENKINS: I have no further  
21 comments.

22 CHAIRPERSON GULYA: Dr. Orloff?

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1 DR. ORLOFF: I haven't heard anything  
2 about any significant risks of the palatal lifting  
3 device. So I certainly think that it remains open to  
4 considering efficacy. And I wouldn't make a blanket  
5 objection to it being over the counter, but, no pun  
6 intended, it doesn't sound like it's very palatable to  
7 the patients if a gag reflex comes into play. I  
8 didn't hear any really contrary or risky issues.

9 CHAIRPERSON GULYA: Thank you.

10 Dr. Li?

11 DR. LI: I don't think there is any data  
12 supporting the use of this device for snoring or sleep  
13 apnea.

14 CHAIRPERSON GULYA: Thank you.

15 Dr. Woodson?

16 DR. WOODSON: I agree, no data to support  
17 these. I can think of some risks. I mean, the little  
18 thing could fall off. You could choke on it. It  
19 could rub a hole in your palate.

20 We use palatal lift devices in patients  
21 with neurogenic swallowing problems or people who have  
22 had part of their tumor gone. In order for them to

1 work, they have to be fit pretty carefully. I would  
2 imagine the same would be true of palatal lift devices  
3 for snoring.

4 CHAIRPERSON GULYA: Wonderful. Thank you.

5 Dr. Zero?

6 MEMBER ZERO: No further comment.

7 CHAIRPERSON GULYA: Thank you.

8 Dr. Terris?

9 DR. TERRIS: No comment other than for the  
10 same objection I had earlier, I wouldn't recommend  
11 this for over-the-counter use.

12 CHAIRPERSON GULYA: Thank you.

13 Dr. Stern?

14 DR. STERN: Carolyn Stern. I don't know  
15 enough about or see enough evidence to make a decision  
16 at this time.

17 CHAIRPERSON GULYA: Thank you.

18 Dr. Calhoun?

19 DR. CALHOUN: Karen Calhoun. Insufficient  
20 data.

21 CHAIRPERSON GULYA: Thank you.

22 Ms. Howe?

1 MS. HOWE: Based on Dr. Demko's report, I  
2 think one concern for consumers would be the gag  
3 reflex. And if that has to be constantly adjusted to  
4 prepare them to handle that issue, that might be a  
5 problem for an over-the-counter product.

6 CHAIRPERSON GULYA: Wonderful segue to Dr.  
7 Demko.

8 DR. DEMKO: Basically, there is  
9 insufficient data. There has never been any proof  
10 that it is really good for obstructive sleep apnea  
11 outside of an unpublished study that they brought to  
12 the FDA years ago.

13 As far as I know, it is probably not even  
14 marketed any more. And I have never seen one in 15-16  
15 years of doing these appliances, never run into anyone  
16 who has ever done one.

17 CHAIRPERSON GULYA: Thank you.

18 Mr. Schechter?

19 MR. SCHECHTER: No further comment.

20 CHAIRPERSON GULYA: Thank you.

21 And Mr. Crompton?

22 MR. CROMPTON: And no comment.

1 CHAIRPERSON GULYA: All right. Thank you.  
2 Dr. Suzuki, if you would lead on the nasal  
3 dilators, please?

4 MEMBER SUZUKI: Jon Suzuki, Dental  
5 Products.

6 Currently the nasal dilators are OTC. My  
7 concern, I guess, based on the discussion --

8 CHAIRPERSON GULYA: For snoring?

9 MEMBER SUZUKI: For snoring. Based on the  
10 discussion so far, I guess my concern that has been  
11 raised is the potential of either a misdiagnosis or a  
12 missed diagnosis for obstructive sleep apnea. So I  
13 think that really raises the spectre of something  
14 else. So I have got my doubts on misdiagnosis.

15 CHAIRPERSON GULYA: Okay. Thank you.

16 Dr. Zuniga?

17 MEMBER ZUNIGA: Again, based on the  
18 literature and publications I saw and the discussion  
19 this morning, it appears that for snoring, there is  
20 some efficacy to it with very little risk. So I would  
21 favor the use of it for snoring.

22 CHAIRPERSON GULYA: Okay. Thank you.

1 Dr. Jenkins?

2 MEMBER JENKINS: Well, for snoring, it is  
3 already over the counter. And they are probably not  
4 going to pull that recommendation back any time soon.

5 I don't think there is any evidence that  
6 I have seen that it is effective in obstructive sleep  
7 apnea. So I wouldn't recommend it for that.

8 CHAIRPERSON GULYA: Okay. Dr. Mair?

9 DR. MAIR: Eric Mair. It is very  
10 interesting looking at Breathe Right strips and other  
11 products like them. We will see that many of the  
12 studies that have gone -- and there aren't very many,  
13 actually, for snoring and for apnea, too. They are  
14 sponsored studies by the company. And there is some  
15 conflict of interest of potential problems. In the  
16 military, we are able to get a little bit around that.  
17 If we get sponsored by them, we go to jail.

18 So we actually did a study looking at  
19 Breathe Right strips. And we published this last  
20 year. What we specifically did, we took a cohort of  
21 patients into our sleep disorders clinic. We took 40  
22 patients. And they had seven days of consecutive

1 sleep studies. The first day data was thrown because  
2 of the first night effect. And then on alternate  
3 days, the patients had different devices, snore aids,  
4 put on.

5 One of the devices that we used was the  
6 Breathe Right stirps. We didn't just ask the partner  
7 or the patient afterwards "How was the snoring?" but  
8 we objectively looked at this, which is no study has  
9 done this yet besides our study. To look at it  
10 objectively, we did it with a device that digitally  
11 records the snore. And then we also looked at it  
12 subjectively, too.

13 And we found that there is absolutely no  
14 difference between wearing Breathe Right strips and  
15 not wearing Breathe Right strips statistically proven  
16 in that area. These were simple snores that we chose.  
17 So there was no change in the AHI.

18 And there also were complications  
19 associated with it. There are patients' subjective  
20 comments: skin irritation, strips uncomfortable, hard  
21 to remove the strips without additional uncomfort,  
22 skin breakdown. These are things that we have to

1 consider.

2 This was a study that we looked at to try  
3 to very objectively look at the potential problems of  
4 these over-the-counter agents just for snoring. And  
5 objectively and subjectively, our cohort of patients  
6 say they don't work.

7 CHAIRPERSON GULYA: Thank you.

8 Dr. Li?

9 DR. LI: I concur.

10 CHAIRPERSON GULYA: Okay. Thank you.

11 Dr. Orloff?

12 DR. ORLOFF: I agree with what has been  
13 said.

14 CHAIRPERSON GULYA: Great. Thank you.

15 Dr. Zero?

16 MEMBER ZERO: No comment.

17 CHAIRPERSON GULYA: Thank you.

18 Dr. Woodson?

19 DR. WOODSON: Yes. I would be real  
20 surprised. I would like to see the original data from  
21 the support of the efficacy of the Breathe Right  
22 strips for snoring because there is his study.

1 I have never had a patient that I cured  
2 snoring by doing a septoplasty. So snoring is kind of  
3 a pharyngeal event. On the other hand, if we  
4 unlabeled it for snoring, people would still try to  
5 use it for that.

6 CHAIRPERSON GULYA: The futility factor  
7 there.

8 DR. WOODSON: Yes.

9 CHAIRPERSON GULYA: Okay. Dr. Stern?

10 DR. STERN: Carolyn Stern. I have never  
11 seen any efficacy, although certainly with the few  
12 side effects of facial rash, there is just more of the  
13 misleadingness that this can be used for snoring when,  
14 in fact, there doesn't seem to be any obvious efficacy  
15 in snoring. So make revisions that there is no  
16 guarantee or something like that.

17 CHAIRPERSON GULYA: Thank you.

18 Dr. Terris?

19 DR. TERRIS: No further comments.

20 CHAIRPERSON GULYA: Thank you.

21 Ms. Howe?

22 MS. HOWE: Betsy Howe. I don't see any

1 reason for removing the over-the-counter status for  
2 the nasal strips. I think in looking at it as a  
3 potential indication for mild OSA, there would be  
4 certainly the need to have studies to see if there is  
5 some objective data to show that, in fact, that can be  
6 a treatment form. But I would certainly not want to  
7 touch the status as it is.

8 ... CHAIRPERSON GULYA: Dr. Calhoun?

9 DR. CALHOUN: I thought we were just  
10 talking about the labeling for snoring or sleep apnea,  
11 not withdrawing the over-the-counter status.

12 CHAIRPERSON GULYA: Well, what we're  
13 looking at, nasal dilators, snoring, sleep apnea,  
14 risk-benefit ratio. It seems a little bit in that  
15 they are already over the counter approved for  
16 snoring.

17 So predominantly I would think we would be  
18 looking at OSA. But we may also for question number  
19 2 be thinking about whether or not we would recommend  
20 to the FDA to modify the labeling for what they have  
21 already for OTC use, to either make it more stringent,  
22 less stringent, less scary, more scary, what have you.

1 DR. CALHOUN: Yes, I agree. There  
2 certainly is no data supporting their labeling for  
3 mild sleep apnea. As far as I can see, there is not  
4 even convincing data for labeling for efficacy in  
5 snoring.

6 CHAIRPERSON GULYA: This is the whole  
7 gamut of sleep dilators. We seem to be focusing a  
8 little bit on the ones the athletes use all the time.

9 Mr. Schechter?

10 MR. SCHECHTER: No further comment.

11 CHAIRPERSON GULYA: Okay. Thank you.

12 Dr. Demko?

13 DR. DEMKO: No further comment.

14 CHAIRPERSON GULYA: Okay. Thank you.

15 Mr. Crompton?

16 MR. CROMPTON: Thank you for pointing that  
17 out. This was a whole category of devices, not just  
18 one strip. I think based on the definition that is  
19 being proposed now for mild and moderate sleep apnea,  
20 there is an opportunity for these sponsors to come  
21 forward with clinical studies. So potentially I think  
22 there is an opportunity now for these nasal dilators

1 to come to the agency with a well-designed clinical  
2 trial.

3 So I think, again, I agree that the  
4 information in the packet did not support OTC, but  
5 that door is now open, I think.

6 CHAIRPERSON GULYA: Okay. Thank you.

7 I think we will be able to wind this up in  
8 time for our 12:30 lunch. I would like to move on to  
9 the cervical pillows. Again, these are  
10 over-the-counter approved for both snoring and mild  
11 obstructive sleep apnea.

12 So I guess we should basically look at  
13 whether or not we would: a) approve a change to OTC  
14 for moderate to severe OSA. And in the later session,  
15 we can talk about labeling changes maybe that we would  
16 recommend for the OTC status for snoring and for mild  
17 OSA.

18 I know everybody is just wondering where  
19 I am going to strike next. I think I will start with  
20 Dr. Li this time.

21 DR. LI: I'm Kasey Li. I'm not in favor  
22 of any labeling of any OTC product that states that it

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1 treats sleep apnea. So that goes with the cervical  
2 pillow as well as any mandibular support devices.

3 In terms of snoring, since it's already  
4 been labeled as OTC, I think it would be difficult to  
5 change that.

6 CHAIRPERSON GULYA: Okay. Thank you.

7 Dr. Orloff?

8 DR. ORLOFF: I just find myself wondering  
9 what happened to the tennis ball in the pajamas  
10 device, if that's on the market or if you have to make  
11 that yourself. But I don't see any evidence for  
12 changing or certainly not increasing the availability  
13 for more severe sleep apnea.

14 The efficacy for mild sleep apnea, the  
15 evidence is pretty weak, but the risk is pretty low,  
16 too, it looks like. So it gets back to the issue of  
17 diagnosing sleep apnea, but I don't have any other  
18 comments on it.

19 CHAIRPERSON GULYA: I think you have to  
20 use a government-approved tennis ball.

21 Dr. Jenkins?

22 MEMBER JENKINS: I don't think there is