

1 interest in the topic at hand; any consulting
2 arrangements or financial interests with medical
3 device firms; and if medical expenses have been paid,
4 by whom.

5 Yes. And I have to read this. I guess
6 this is going to be a little bit redundant. My
7 apologies.

8 EXECUTIVE SECRETARY S. THORNTON: No, you
9 don't.

10 CHAIRPERSON GULYA: I don't have to read
11 this again -- oh, thank you -- which is basically
12 going through again the medical expenses issue.

13 Now, as I understand it, we have one
14 presenter, Mr. Edward Grandi, one who is registered.
15 And although we have 30 minutes in this session, in
16 fairness for the individuals who had to adhere to a
17 5-minute time period in the morning session, it would
18 be greatly appreciated if you could do the same. And
19 we have a little device here that will kind of keep us
20 both honest. So if you could proceed, please?

21 MR. GRANDI: Yes. Thank you. My name is
22 Edward Grandi. I'm the Executive Director of the

1 American Sleep Apnea Association, Washington, D.C. a
2 national patient interest organization dedicated to
3 educating the general public and the medical community
4 on the diagnosis and treatment of sleep apnea. We are
5 also committed to supporting people in treatment
6 through a network of support groups around the
7 country.

8 I am interested in this topic because our
9 organization is dedicated to the issue of sleep apnea.
10 I have no financial interest. And I paid my own
11 expenses to get here.

12 We appreciate the opportunity to comment
13 on the joint meeting of the FDA Dental Products and
14 Ear, Nose, and Throat Device Panels. From all of the
15 things that I have heard during the course of the day,
16 I have no quibbles with anything that anybody has
17 said.

18 Certainly I think taking a more cautious
19 approach with regard to taking devices that are
20 currently prescribed devices and making them
21 over-the-counter devices is very prudent. I don't
22 think that anybody benefits by having devices that are

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1 available that could possibly injure people by making
2 them more generally available.

3 So to that extent, I would encourage use
4 of very strict clinical data in looking at new
5 devices. Perhaps if the mandibular devices that
6 currently have not been considered, if they do come up
7 for consideration, that strict standards would be
8 applied in terms of their use.

9 I would also encourage the use of
10 screening devices, either questionnaires or other
11 types of devices, for people who have snoring and
12 perhaps are not sure whether they have sleep apnea or
13 not, encourage them, as suggested by Ms. Howe, either
14 to visit our Web site or to visit the other Web sites
15 that are available that provide access to
16 questionnaires and devices and other means for
17 determining whether they're at risk of sleep apnea and
18 if they are at risk of sleep apnea, encourage them to
19 visit a medical doctor who can help them get a
20 diagnosis.

21 I will close by saying that access to
22 sleep studies is an issue. Last week Medicare was

1 considering the question of portable home studies. I
2 was present at that meeting as well. Certainly by
3 raising awareness of sleep apnea, we are also
4 increasing the need for access to diagnosis and then
5 ultimately to affordable treatment.

6 I would hope that affordable treatment is
7 not done at the expense of a population who is already
8 suffering a great deal. Thank you for this
9 opportunity to speak.

10 CHAIRPERSON GULYA: Okay. Thank you, Mr.
11 Grandi.

12 Is there anybody else out there who wishes
13 to take this opportunity to address the panel? Sally?

14 EXECUTIVE SECRETARY S. THORNTON: Just for
15 the record, I wanted to make a note of the fact that
16 there were two people who had registered to speak but,
17 unfortunately, were unable to come here to present in
18 person. And their comments have been made available
19 to the panel and to the transcriber. So they will
20 appear in the record. Those people are Barry Krakow,
21 M.D., Medical Director of Sleep and Human Health
22 Institute and the Maimonides Sleep Arts & Sciences