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1 DR. DAVIS: Thank you. And thank you
2 for putting up with the audiovisual difficulty.
3 Edward Grandi.

4 MR. GRANDI: Good morning. My name is
5 Edward Grandi. I am the executive director of the
6 American Sleep Apnea Association located in
7 Washington, D.C. The ASAA is a nonprofit patient
8 interest organization dedicated to seeing that all
9 patients with sleep apnea are diagnosed and
10 treated. Thank you for the opportunity to present
11 the American Sleep Apnea Association's view on
12 portable multichannel home testing devices as an
13 alternative to facility-based polysomnography in
14 the evaluation of obstructive sleep apnea. In the
15 interest of full disclosure, I would like to
16 acknowledge that the AASA has received financial
17 support from a number of companies involved in the
18 treatment of obstructive sleep apnea. I
19 personally do not hold any stock in any company in
20 the sleep field other than what may be in an
21 individual retirement account, and the association
22 paid for my expenses to attend this morning.
23 Sleep disordered breathing, including
24 sleep apnea and obstructive airway resistance
25 syndrome, is a common disorder that affects

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1 millions of Americans of all ages. We believe
2 that it is substantially underdiagnosed, in part
3 because most of the common symptoms, snoring and
4 falling asleep easily and/or sometimes
5 inappropriately are not recognized as symptoms of
6 a potentially serious medical disorder.
7 Consequences of untreated sleep apnea may be
8 significant, including sleepiness, high blood
9 pressure and cardiovascular disease, diabetes
10 mellitus, morning headaches, feelings of
11 depression, impotence and memory problems.
12 Once diagnosed, a patient may be
13 prescribed a course of treatment. Treatment
14 options include oral appliances, weight loss,
15 positional therapy, surgery, and the use of
16 continuous positive airway pressure. Which
17 treatment option is best for the patient depends
18 upon the severity of sleep apnea and other aspects
19 of the patient's medical history. If treated on a
20 consistent basis, studies now show that some of
21 the serious consequences of sleep apnea can be
22 reversed.
23 The AASA welcomes the discussion of
24 multichannel home sleep testing devices as an
25 alternative to facility-based polysomnography in

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1 the evaluation of OSA. Facility-based
2 polysomnography does offer the diagnostician
3 considerably more information than is currently
4 available from multichannel home sleep test
5 devices, but the concern of the AASA is access to
6 appropriate diagnostic services for the millions
7 of Americans who are as yet undiagnosed.
8 Our organization has had measurable
9 success in providing educational resources to the
10 public and medical community which has increased
11 awareness of this disorder. Now that they're
12 aware, there is a need to get a sleep study done.
13 It is unrealistic to believe that everyone who is
14 made aware of the risk of OSA will rush to get a
15 sleep study done. For some, what keeps them from
16 going is denial. For others, it's a question of
17 accessibility; they may not live close enough to a
18 sleep lab for it to be convenient. There are also
19 those in need of a sleep study who do not have
20 health insurance or the financial resources to pay
21 for PSG. Given any obstacle, however small, a
22 person needing a study may put off getting it
23 done.
24 We are particularly concerned for the
25 uninsured population. Anecdotal evidence

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1 collected from telephone conversations and e-mail
2 correspondence leads us to believe that access for
3 diagnosis and treatment is a problem.
4 The use of portable multichannel home
5 testing devices could increase accessibility to
6 sleep studies and if done at a reduced cost,
7 decrease the expense. We believe that providing
8 access to a sleep study as the primary means of
9 diagnosis as to whether an individual has sleep
10 apnea or not is a significant part of what is most
11 important.
12 What also matters, beyond that the
13 diagnostic test not stand in the way of access, is
14 that whatever testing is done be coupled with
15 professional input. While this occurs almost
16 automatically with a sleep test done in a
17 laboratory, the issues raised by portable
18 monitoring are inextricably linked with the nature
19 of reimbursed professional care coupled with the
20 actual performance of the test. The best care
21 currently available for obstructive sleep apnea
22 requires both readily accessible testing and
23 incentives for the professional sleep specialist
24 to interact with the patient before and after
25 testing.

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1 We encourage the Medicare Coverage
2 Advisory Committee to keep this in mind while they
3 consider the issue. Thank you again for this
4 opportunity to speak to the committee today.
5 DR. DAVIS: Thank you. We had
6 scheduled a break for 10:30, so we will go ahead
7 and take a ten-minute break now and then pick up
8 with the other scheduled presenters immediately
9 after the break.
10 (Recess.)
11 DR. DAVIS: Dr. Coppola, let's give the
12 members of the committee another 30 seconds or so
13 to take their seats. Please proceed.
14 DR. COPPOLA: Thank you. My name is
15 Michael Coppola. I'm a practicing pulmonologist
16 in Springfield, Massachusetts, and I have devoted
17 the past 16 years to treating sleep apnea
18 patients. I treat 30 to 50 patients a week and
19 have used portable and facility-based testing, and
20 I can tell you like all the other speakers, I get
21 paid a lot of money to read in-facility
22 polysomnography.
23 I am on the medical advisory board of
24 ResMed Corporation and I am on the board of
25 directors of the American Sleep Apnea Association.